Pediatric Labeling Changes through August 31, 2011

N=420

n=387 with New Pediatric Studies; n=33 with No New Pediatric Studies

BPCA only = 146 BPCA + PREA = 48; PREA only = 179; Rule = 47

This table does not include Safety Waiver labeling changes.

Safety Waiver Labeling Change Table Link (pending)

The table is in reverse chronological order by the labeling date.

	Labeling Date♦	Trade Name	Generic or Proper (Biologics●) Name	Indication(s) Studied	Product Labeling	Labeling Changes	BPCA (B)/ PREA (P)/ Rule (R)	Sponsor	PE Granted Date	N N P S
1.	7/22/2011	GAMMA GARD LIQUID	Immune Globulin Infusion (Human)●	Treatment of patients with primary immunodeficiency associated with defects in humoral immunity in adults and pediatric patients two years of age or older		See Package Insert for new information on biologics	P	Baxter	NA	
2.	7/15/2011	Topamax	topiramate	Monotherapy for partial onset or primary generalized tonic-clonic seizures	Labeling	▪ Expanded age range down to 2 years; previously approved for monotherapy for partial onset or primary generalized tonic-clonic seizures in patients10 years and older ▪ Information on weight based dosing in 2 to < 10 years ▪ Postmarketing study	P	Janssen	NA	
3.	6/15/2011	Zenpep Delayed-Release Capsules	pancrelipase	Postmarketing study	Labeling	• New dosage strength of 3,000 USP lipase units to allow for dosing in infants less than 12 months • Postmarketing study	P	Eurand Pharmaceuticals	NA	
4.	6/10/2011	Creon Delayed-Release Capsules	pancrelipase	Postmarketing study	Labeling	• New dosage strength of 3,000 USP lipase units to allow for dosing in infants less than 12 months • Postmarketing study	P	Abbott	NA	
5.	5/17/2011	Faslodex Injection	fulvestrant	Use in girls with	Labeling	• Efficacy has not been demonstrated in girls with McCune-Albright	B	AstraZeneca	2/1/2011	

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				progressive precocious puberty associated with McCune-Albright Syndrome		Syndrome associated with progressive precocious puberty • Information on dosing, adverse reactions, pharmacokinetics and clinical trial				
6.	5/6/2011	Plavix	clopidogrel bisulfate	Reduction of the incidence of thrombosis in children with systemic to pulmonary artery shunts for palliation of cyanotic congenital heart disease	Labeling	• Safety and effectiveness in pediatric populations have not been established • A randomized, placebo-controlled trial did not demonstrate a clinical benefit in neonates and infants with cyanotic congenital heart disease palliated with a systemic-to-pulmonary arterial shunt.	B	sanofi-aventis	1/20/2011	
7.	4/29/2011	Nexium I.V.	esomeprazole sodium	Treatment of Gastroesophageal Reflux Disease (GERD) with erosive esophagitis	Labeling	• Extended indication from adults to pediatric patients 1 month to 17 years • Use in pediatric patients 1 month to 17 years is supported by studies in adults, and PK and PD studies performed in pediatric patients • Effectiveness has not been established in patients less than 1 month of age • Information on dosing, adverse reactions, pharmacokinetics and clinical trial • Postmarketing study	P	AstraZeneca	NA	
8.	4/29/2011	Kytril Injection	granisetron hydrochloride	Prevention of postoperative nausea and vomiting	Labeling	• Safety and efficacy have not been established in pediatric patients for the prevention of postoperative nausea and vomiting (PONV) • Due to the lack of efficacy and the QT prolongation observed in this trial, use for the prevention of PONV in children is not recommended • Information on postmarketing clinical trial, adverse reactions • Postmarketing PREA required study	P	Hoffman-LaRoche	NA	
9.	4/25/2011	Lamictal XR Extended-Release tablets	lamotrigine	Monotherapy in patients 13 years of age and older with partial seizures who are receiving therapy with a single antiepileptic drug (AED)	Labeling	• Approved for conversion to monotherapy in patients ≥13 years of age with partial seizures receiving treatment with a single antiepileptic drug (AED). • Safety and effectiveness have not been established (1) as initial monotherapy or (2) for simultaneous conversion to monotherapy from two or more concomitant AEDs • Information on conversion to monotherapy, adverse reactions, clinical trial • New indication	P	GlaxoSmithKline	NA	
10.	4/22/2011	Menactra	Meningococcal Polysaccharide (Serogroups A,	Active immunization of individuals	Package Insert	See Package Insert for new information on biologics	P	Sanofi Pasteur	NA	

	Labeling Date♦	Trade Name	Generic or Proper (Biologics●) Name	Indication(s) Studied	Product Labeling	Labeling Changes	BPCA (B)/ PREA (P)/ Rule (R)	Sponsor	PE Granted Date	N N P S
			C, Y and W - 135) Diphtheria Toxoid Conjugate Vaccine●	9 months through 55 years of age for the prevention of invasive meningococcal disease caused by Neisseria meningitidis serogroups A, C, Y and W - 135						
11.	4/15//2011	Actemra	tocilizumab	Treatment of active Systemic Juvenile Idiopathic Arthritis (SJIA) in patients two years of age and older.	Labeling	• Approved for the treatment of active SJIA in patients 2 years and older • Safety and effectiveness in pediatric patients with conditions other than SJIA have not been established • Children < 2 years have not been studied • Interruption of dosing may be needed for management of dose-related laboratory abnormalities including elevated liver enzymes, neutropenia, and thrombocytopenia • Liver enzyme elevation, low neutrophil count, low platelet count and lipid elevations are noted with Actemra treatment in the SJIA population. • The most common adverse events Actemra treated patients in the controlled portion of the study were upper respiratory tract infection, headache, nasopharygitis and diarhea • Information on dosing, lab parameters, adverse reactions, clinical trial • New indication	P	Genentech	NA	
12.	4/6/2011	Invega	paliperidone	Treatment of schizophrenia	Labeling	• Extended treatment of schizophrenia indication from adults to adolescents 12-17 years • Safety and effectiveness for the treatment of schizophrenia in patients < 12 years have not been established. • Safety and effectiveness for the treatment of schizoaffective disorder in patients < 18 years have not been studied • In the adolescent schizophrenia trial, there was no clear enhancement to efficacy at escalation to higher doses (e.g., 6 mg for patients weighing less than 51 kg and 12 mg for patients weighing 51 kg or greater) while adverse events were dose-related • In the 6-week, placebo-controlled study in adolescents with schizophrenia, the incidences of extrapyramidal symptoms related adverse events showed a similar dose-related pattern to those in the adult studies. There were notably higher incidences of dystonia, hyperkinesia, tremor, and parkinsonism in adolescents as compared to the adult studies	B	Ortho McNeil	1/5/2011	

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						• Adverse reactions in the adolescent trial included somnolence, akathisia, tremor, dystonia, cogwheel rigidity, anxiety, weight gain, and tachycardia • Information on dosing, adverse events, clinical trial				
13.	3/17/2011	Alimta	pemetrexed disodium	Refractory and recurrent solid tumors, including osteosarcoma, Ewing sarcoma/peripheral PNET, rhabdomyosarcoma, and neuroblastoma	Labeling	• Efficacy in pediatric patients has not been demonstrated • No responses were observed among the 72 patients in the Phase 2 trial • Information on dosing, clinical trial, adverse events and pharmacokinetics	B	Lilly	12/3/2010	
14.	3/14/2011	Gadavist	gadobutrol	To detect and visualize areas with disrupted blood brain barrier (BBB) and/or abnormal vascularity of the central nervous system	Labeling	• Safety and efficacy have been established in children 2 - 17 years • Safety and effectiveness have not been established in children <2 years • Information on dosing, adverse events, pharmacokinetics, and clinical trials	P	Bayer	NA	
15.	2/25/2011	Intuniv	guanfacine	Adjunctive treatment with long-acting oral psychostimulants for the treatment of ADHD	Labeling	• Approved for use as adjunctive therapy with stimulants for the treatment of ADHD in pediatric patients 6 years and older • Information on adverse reactions and clinical trial • New indication	P	Shire	NA	
16.	2/3/2011	Makena	hydroxyprogesterone caproate	Reduce the risk of preterm birth	Labeling	• Safety and effectiveness in pediatric patients <16 years have not been established • A small number of women < 18 years were studied; safety and efficacy are expected to be the same in women aged 16 years and above as for users 18 years and older • Information on clinical trial	P	Hologic, Inc.	NA	
17.	1/30/2011	MENVEO	Meningococcal (Groups A, C, Y, and W-135) Oligosaccharide Diphtheria	Active immunization to prevent invasive meningococca	Package Insert	See Package Insert for new information on biologics	P	Novartis	NA	

	Labeling Date♦	Trade Name	Generic or Proper (Biologics●) Name	Indication(s) Studied	Product Labeling	Labeling Changes	BPCA (B)/ PREA (P)/ Rule (R)	Sponsor	PE Granted Date	N N P S
			CRM197 Conjugate Vaccine●	l disease caused by *Neisseria meningitidis* serogroups A, C, Y and W-135						
18.	1/19/2011	Nasonex	mometasone	Treatment of nasal polyps	Labeling	• Safety and effectiveness for the treatment of nasal polyps in children < 18 years have not been established • A trial in pediatric patients 6 to 17 years did not support the efficacy of Nasonex Nasal Spray in the treatment of nasal polyps • The adverse events were similar to adults • Information on clinical trial	P	Schering Plough	NA	
19.	1/18/2011	Natroba Topical Suspension	spinosad	Treatment of head lice infestation in patients 4 years of age and older.	Labeling	• Safety and effectiveness have been established in pediatric patients 4 years of age and older • Safety in pediatric patients < 4 years has not been established. • Not recommended in pediatric patients< 6 months because of the potential for increased systemic absorption • Natroba contains benzyl alcohol which has been associated with serious adverse reactions and death in neonates and low birth-weight infants. Premature and low-birth weight infants, as well as patients receiving high dosages, may be more likely to develop toxicity • Information on clinical trials, adverse reactions • New drug	P	ParaPRO	NA	
20.	12/22/2010	GARDASIL	Human Papillomavirus Quadrivalent (Types 6, 11, 16, 18) Vaccine, Recombinant●	Prevention of anal cancer and associated precancerous lesions caused by HPV types 16 and 18	Package Insert	See Package Insert for new information on biologics	P	Merck	NA	✓
21.	12/21/2010	INOmax for Inhalation	nitric oxide	Prevention of bronchopulmonary dysplasia	Labeling	• INOmax is not indicated for prevention of BPD in preterm neonates ≤ 34 weeks gestational age. • Efficacy for the prevention of BPD in preterm infants was not established in three ldouble-blind, placebo-controlled clinical trials in a total of 2,149 preterm infants • Information on clinical trials, adverse reactions	B	INO Therapeutics	11/2/2010	
22.	12/15/2010	Uroxatral extended-release tablets	alfuzosin	Elevated detrusor leak point pressure of neurologic origin	Labeling	• Uroxatral is not indicated for use in the pediatric population • Efficacy was not demonstrated in a randomized, double-blind, placebo-controlled, efficacy and safety trial conducted in 172 patients ages 2 to	B	sanofi-aventis	9/7/2010	

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						16 years using pediatric formulations				
23.	11/19/2010	Moxeza ophthalmic solution	moxifloxacin hydrochloride	Bacterial conjunctivitis	Labeling	• Approved for use in patients 4 months and older • The safety and effectiveness have not been established in patients <4 months of age • There is no evidence that the ophthalmic administration of moxifloxacin has any effect on weight bearing joints, even though oral administration of some quinolones has been shown to cause arthropathy in immature animals • Information on clinical study, adverse reactions • New dosage form	P	Alcon	NA	
24.	11/10/2010	Vyvanse	lisdexamfetamine	ADHD	Labeling	• Expanded indication to include adolescent patients ages13-17 years; previously approved for use in 6-12 years • Most common adverse reactions were decreased appetite, insomnia, and decreased weight • Information on clinical trial, adverse reactions	P	Shire	NA	
25.	11/2/2010	Ofirmev Injection	acetaminophen	Management of mild-to-moderate pain, for the management of moderate-to-severe pain with adjunctive opioid analgesics, and for the reduction of fever	Labeling	• The safety and effectiveness of Ofirmev for the treatment of acute pain and fever in pediatric patients ages 2 years and older is supported by evidence from adequate and well-controlled studies of Ofirmev in adults. Additional safety and PK data was collected in 355 from premature neonates to adolescents. • The effectiveness of Ofirmev for the treatment of acute pain and fever has not been studied in pediatric patients < 2 years of age. • The PK exposure of Ofirmev observed in children and adolescents is similar to adults, but higher in neonates and infants. Dosing simulations from PK data in infants and neonates suggest that dose reductions of 33% in infants 1 month to < 2 years of age, and 50% in neonates up to 28 days, with a minimum dosing interval of 6 hours, will produce a PK exposure similar to that observed in children age 2 years and older • Most common adverse reactions in pediatric patients were nausea, vomiting, constipation, pruritus, agitation, and atelectasis. • Information on dosing, clinical studies, adverse reactions and PK parameters • New dosage form and route of administration	P	Cadence Pharms	NA	
26.	10/21/2010	Lo Loestrin Fe	norethindrone acetate/ ethinyl estradiol	Prevention of pregnancy	Labeling	• Safety and efficacy have been established in women of reproductive age. Safety and efficacy are expected to be the same for postpubertal adolescents <18 years and for users ≥18 years • Use before menarche is not indicated • New dose and dosing regimen	P	Warner Chilcott	NA	✓
27.	10/5/2010	Aridol	mannitol	Assessment	Labeling	• New indication in patients 6 years and older	P	Pharmaxis	NA	

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		Powder for Inhalation		of bronchial hyperresponsiveness in patients without clinically apparent asthma		• Efficacy assessed in a total of 246 children and adolescents 6 to 17 years in 2 clinical trials • Bronchial challenge testing should not be performed in children < 6 years due to their inability to provide reliable spirometric measurements • Adverse events similar to adults • Information on adverse events and clinical studies • New indication, dosage form, and route of administration				
28.	9/28/2010	Kapvay Extended Release Tablets	clonidine	Treatment of attention deficit hyperactivity disorder (ADHD) as monotherapy and as adjunctive therapy to stimulant medications	Labeling	• New indication in children 6 years and older • Efficacy is based on 2 clinical trials in children and adolescents 6 -17 years • Kapvay has not been studied in children with ADHD < 6 years • Kapvay can cause dose related decreases in blood pressure and heart rate • Common adverse events reported in clinical trials included somnolence, fatigue, upper respiratory tract infection irritability, throat pain, insomnia, nightmares, emotional disorder. In fixed dose pediatric monotherapy study, 31% of patients treated with 0.4 mg/day and 38% treated with 0.2 mg/day vs 7% of placebo treated patients reported somnolence. • Kapvay is an extended-release tablet formulation of clonidine; therefore, it is not to be used interchangeably with the immediate-release formulation • Information on adverse events, and clinical trials • New indication	P	Shionogi	NA	
29.	9/24/2010	Beyaz	drospirenone/ ethinyl estradiol	Prevention of pregnancy; premenstrual dysphoric disorder; moderate acne vulgaris ≥14 years who have achieved menarche; to raise folate levels in a pregnancy conceived while on or shortly after discontinuing the product	Labeling	• Safety and efficacy have been established in women of reproductive age. Safety and efficacy are expected to be the same for postpubertal adolescents <18 years and for users ≥18 years • Use before menarche is not indicated • New combination	P	Bayer	NA	✓
30.	9/8/2010	Protopam	pralidoxime	Treatment of poisoning due to organophosph	Labeling	• Expanded indication from adults to pediatrics • Efficacy extrapolated from adult population and supported by nonclinical studies, PK studies in adults and experience in the pediatric population	P	Baxter	NA	

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				ates (e.g., nerve agents)		• Information on IV and IM dosing, and adverse events				
31.	9/3/2010	Zyrtec Allergy Orally Disintegrating Tablets	cetirizine	Temporary relief of symptoms due to hay fever or other upper respiratory allergies OTC		• Approved for use in 6 years and older • No clinical studies submitted • New dosage form	P	McNeil Consumer Healthcare	NA	✓
32.	8/27/2010	Augmentin XR	amoxicillin/clavulanate potassium	Community-acquired pneumonia or acute bacterial sinusitis	Labeling	• Expanded indication from adults to children weighing ≥ 40 kg who are able to swallow tablets • Use in children is supported by evidence from trials of adults with additional data from a pediatric PK study • Adverse events similar to adults • Information on dose, and PK parameters • Information added to Clinical Pharmacology and Pediatric Use	P	GlaxoSmith Kline	NA	
33.	8/13/2010	ella	ulipristal acetate	Prevention of pregnancy following unprotected intercourse or a known or suspected contraceptive failure	Labeling	• Safety and efficacy have been established in women of reproductive age. Safety and efficacy are expected to be the same for post pubertal adolescents <18 years and for users 18 years and older. • Use of ella before menarche is not indicated • New drug	P	Laboratoire HRA Pharma	NA	✓
34.	7/28/2010	Lastacaft Ophthalmic Solution	alcaftadine	Prevention of itching associated with allergic conjunctivitis.	Labeling	• Safety and effectiveness in patients >2 years were established in controlled clinical trials • Safety and effectiveness in pediatric patients< 2 years have not been established • New drug	P	Vistakon Pharmaceuticals,	NA	
35.	6/29/2010	Daytrana	methylphenidate	ADHD	Labeling	• Expanded pediatric indication to include adolescent patients ages13-17 years • The most commonly reported adverse reactions in a trial in patients 13-17 years included appetite decreased, nausea, insomnia, weight decreased, dizziness, abdominal pain, and anorexia. The majority of patients had erythema at the application site • Information on PK parameters, Adverse Event profile and clinical studies	P	Shire	NA	
36.	6/22/2010	Dulera Inhalatio	mometasone furoate and	Asthma	Labeling	• Safety and effectiveness have been established in patients 12 years and older in 3 clinical studies	P	Schering	NA	

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		n Aerosol	formoterol fumarate			• Safety and efficacy have not been established in children <12 years • Data from clinical trials suggest that LABA increase the risk of asthma-related hospitalization in pediatric and adolescent patients • Information on adverse events and clinical studies • New combination				
37.	6/22/2010	Isopto Carpine	pilocarpine hydrochloride	Reduction of elevated intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension; management of acute angle closure glaucoma; prevention of postoperative elevated IOP associated with laser surgery and induction of miosis	Labeling	• Safety and effectiveness in pediatric patients have been established • Not recommended in pediatric patients diagnosed with glaucoma due to anterior segment dysgenesis or uveitis • Caution is advised in pediatric patients with primary congenital glaucoma for control of IOP as cases of a paradoxical increase in IOP have been reported. • Adverse events similar to adults • New dosage form	P	Alcon	NA	✓
38.	6/3/2010	Zylet	loteprednol etabonate and tobramycin	Eye lid inflammation	Labeling	• Efficacy was not demonstrated in a study of pediatric patients 0-6 years	P	Bausch and Lomb	NA	
39.	5/27/2010	Advil Congestion Relief	ibuprofen /phenylepherine HCl	Temporary relief of symptoms associated with cold and flu		• Indicated for use in children 12 years and older • Approval and age range based on monograph for decongestants and previous studies for ibuprofen • Do not use in children < 12 years because this product contains too much medication for this age • New drug	P	Wyeth	NA	✓
40.	5/26/2010	Nasonex	mometasone	Nasal congestion associated with seasonal allergic rhinitis	Labeling	• New indication in pediatric patients 2 years and older • Safety and effectiveness evaluated in 3 clinical studies in 12 years and older. Use in pediatric patients 2 - 11 years is supported by data from other pediatric clinical studies • Safety and effectiveness for any use in patients < 2 years have not been established • Information on dosing, adverse reactions, and clinical studies in 12 years and older	P	Schering-Plough	NA	

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						• New indication				
41.	5/18/2010	Zymaxid	gatifloxacin	Bacterial conjunctivitis	Labeling	• Safety and effectiveness have been demonstrated in clinical trials for the treatment of bacterial conjunctivitis in pediatric patients 1 year and older • The safety and effectiveness in infants < 1year have not been established • Information on adverse reactions and clinical trials • New drug	P	Allergan	NA	
42.	5/13/2010	Taxotere	docetaxel	Solid Tumors	Labeling	• Efficacy in pediatric patients as monotherapy or in combination has not been established. • Taxotere has been studied in a total of 289 pediatric patients: 239 in 2 trials with monotherapy and 50 in combination treatment with cisplatin and 5-fluoruracil • The overall safety profile in pediatric patients receiving monotherapy or combination treatment was consistent with the safety profile in adults • Information on dosing, clinical trials and PK parameters	B	Sanofi-aventis	3/17/2010	
43.	5/7/2010	Omnaris	ciclesonide	Postmarketing study	Labeling	• Information on clinical study to assess effect of orally inhaled ciclesonide on growth	P	Sepracor	NA	
44.	5/6/2010	Natazia	estradiol valerate and estradiol valerate/dienogest	Prevention of pregnancy	Labeling	• Safety and efficacy have been established in women of reproductive age. Safety and efficacy for post pubertal adolescents < 18 are expected to be the same as for 18 years and older • Use of this product before menarche is not indicated • New drug	P	Bayer	NA	✓
45.	4/12/2010	Pancreaze	pancrelipase	Treatment of exocrine pancreatic insufficiency due to cystic fibrosis or other conditions	Labeling	• Safety and efficacy assessed in 2 studies that included patients 6-30 months and 8--17 years • Safety and efficacy for use in all pediatric age groups based on information from the literature and clinical experience with different formulations of pancrelipase containing the same active ingredient • High doses of pancreatic enzyme products have been associated with fibrosing colonopathy in children <12 years of age • Adverse reactions similar to adults • Capsule should be swallowed whole. For infants or patients unable to swallow intact capsules, the contents may be sprinkled on soft acidic food such as applesauce • Information on dosing and clinical studies • Not interchangeable with other pancrelipase products • New drug	P	Ortho-McNeil-Janssen	NA	

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46.	3/24/2010	Viread	tenofovir disoproxil fumarate	Treatment of HIV infection in combination with other antiretroviral agents	Labeling	• Expanded indication from adults to pediatric patients 12- <18 years • Safety and effectiveness in patients < 12 years have not been established • In a clinical study of HIV-1 infected adolescents bone effects were similar to adults • The adverse reactions in trial in adolescents were consistent with those observed in clinical trials in adults • Information on dosing in adolescents weighing ≥35 kg, adverse reactions, and PK parameters	B, P	Gilead	NA	
47.	3/17/2010	Differin Lotion	adapalene	Acne	Labeling	• Safety and effectiveness established in 2 clinical studies in patients 12 years and older • Safety and effectiveness in pediatric patients less than 12 years have not been established • New dosage form	P	Galderma	NA	
48.	3/17/2010	MultiHance Injection	gadobenate dimeglumine	Intravenous use in magnetic resonance imaging	Labeling	• Extended indication from adults to pediatric patients 2 years and older • Safety and effectiveness in pediatric patients less than 2 years have not been established • Patients less than 2 years may be at increased risk of nephrogenic systemic fibrosis related to gadolinium due to immature kidney function • Adverse events similar to adult patients • Information on adverse events, PK, and clinical studies • New indication	P	Bracco Diagnostics	NA	
49.	2/24/2010	Prevnar 13	Pneumococcal 13-valent Conjugate Vaccine (Diphtheria CRM197 Protein) ●	Active immunization for the prevention of invasive disease caused by Streptococcus pneumoniae serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F, and for the prevention of otitis media caused by serotypes 4, 6B, 9V, 14, 18C, 19F, and	Package Insert	See Package Insert for new information on biologics	P	Wyeth	NA	

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				23F						
50.	2/22/2010	TamiFlu	oseltamivir	Prophylaxis of influenza	Labeling	• Information on postmarketing clinical study in patients 1 to 12 years	P	Hoffmann-La Roche Inc.	NA	
51.	2/19/2010	MENVEO	Meningococcal (Groups A, C, Y, and W-135) Oligosaccharide Diphtheria CRM197 Conjugate Vaccine●	Active immunization to prevent invasive meningococcal disease caused by *Neisseria meningitidis* serogroups A, C, Y and W-135	Package Insert	See Package Insert for new information on biologics	P	Novartis	NA	
52.	2/4/2010	Benicar	olmesartan	Hypertension	Labeling	• Expanded indication from adults to pediatric patients 6 years and older • Information on preparation of an oral suspension • Adverse events similar to adult patients • Information on dosing, adverse reactions, pharmacokinetics, and clinical studies	B, P	Daiichi Sankyo	10/7/2009	
53.	1/29/2010	Lamictal XR	lamotrigine	Adjunctive therapy for Primary Generalized Tonic-Clonic seizures	Labeling	• New indication for adjunctive therapy for primary generalized tonic-clonic seizures in patients ≥ 13 years of age • Safety and effectiveness for any use in patients < 13 years have not been established • Information on dosing, adverse reactions, and clinical studies	P	GlaxoSmith Kline	NA	
54.	1/25/2010	Sandostatin and Sandostatin LAR	octreotide	Weight loss due to hypothalamic obesity from cranial insult	Labeling Labeling	• Post-marketing reports of hypoxia, necrotizing enterocolitis, and death in children added to Pediatric Use. The relationship of these events to octreotide has not been established. • Pediatric Use subsection of Sandostatin labeling harmonized with Sandostatin LAR labeling	B	Novartis	1/12/2006	✓
55.	1/4/2010	Xolair	omalizumab	Moderate to severe persistent asthma who have a positive skin test or in vitro reactivity to a perennial aeroallergen and whose symptoms are inadequately		• Safety and effectiveness were evaluated in 2 studies in 926 asthma patients 6 to <12 years of age. The risk-benefit assessment does not support use in patients 6 to <12 years considering the risk of anaphylaxis and malignancy seen in Xolair-treated patients ≥12 years and the modest efficacy of Xolair in the pivotal pediatric study • Studies in patients 0-5 years were not required due to safety concerns of anaphylaxis and malignancy • Information added to Pediatric Use	P	Genentech	NA	

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				controlled with inhaled corticosteroids .						
56.	12/24/2009	Famvir	famciclovir	Treatment of children 1 month – 12 years of age w/ herpes simplex (HSV) & 1 – 12 years w/ varicella zoster (VSV)	Labeling	• Available data are insufficient to support the use of famciclovir for the treatment of children with chickenpox or infections due to HSV • The PK profile and safety were studied in 2 open-label studies: (1) a single-dose PK and safety study in infants 1 month to <1 year of age who had an active herpes simplex virus (HSV) infection or who were at risk for HSV infection and (2) a single-dose PK, multiple-dose safety study in children 1 to <12 years of age with clinically suspected HSV or varicella zoster virus (VZV) infection • Information added to Pediatric Use	B, P	Novartis	9/21/2009	
57.	12/22/2009	Flomax	tamsulosin	Treatment of elevated detrusor leak point pressure associated with neurological disorder	Labeling	• Efficacy and positive benefit/risk was not demonstrated in 2 studies (a randomized, double-blind, safety and efficacy study and an open label safety study) conducted in patients 2 -16 years • The most frequently reported adverse events from the 2 studies were urinary tract infection, vomiting, pyrexia, headache, nasopharyngitis, cough, pharyngitis, influenza, diarrhea, abdominal pain, and constipation. • Information added to Pediatric Use	B	Boehringer Ingelheim	9/17/2009	
58.	12/22/2009	Topamax	topiramate	Adjunctive Treatment for Partial Onset Epilepsy in Infants and Toddlers 1 to 24 months	Labeling	• Effectiveness was not demonstrated as adjunctive therapy in a randomized, double-blind trial in infants/toddlers 1 to 24 months of age with refractory partial onset seizures • Trials in infants/toddlers 1 to 24 months suggested some adverse reactions/toxicities not previously observed in older pediatric patients and adults; i.e, growth/length retardation, certain clinical laboratory abnormalities, and other adverse reactions/toxicities that occurred with a greater frequency and/or greater severity than had been recognized previously from studies in older pediatric patients or adults for various indications. • Information added to Warnings and Precautions and Pediatric Use	B	Ortho-McNeil-Janssen	7/24/2008	
59.	12/22/2009	Topamax	topiramate	Migraine Prophylaxis	Labeling	• Safety and effectiveness for migraine prevention in pediatric patients have not been established • Dose-related increased shift in serum creatinine in adolescent patients occurred in a clinical study • Information added to Warnings and Precautions and Pediatric Use	P	Ortho-McNeil-Janssen	NA	
60.	12/14/2009	Daytrana	methylphenidate	Postmarketing safety study	Labeling	• Information added to Warnings and Adverse Reactions on skin reactions observed in a postmarketing dermal study in pediatric patients	P	Shire	NA	
61.	12/4/2009	Zyprexa	olanzapine	Treatment of manic or mixed episodes of	Labeling	• Extended schizophrenia and manic or mixed episodes of bipolar I disorder indications from adults to adolescents 13–17 years of age • Safety and effectiveness in children < 13 years of age have not been established	B	Lilly	1/10/2007	✓

	Labeling Date♦	Trade Name	Generic or Proper (Biologics●) Name	Indication(s) Studied	Product Labeling	Labeling Changes	BPCA (B)/ PREA (P)/ Rule (R)	Sponsor	PE Granted Date	N N P S
				bipolar I disorder and schizophrenia in adolescents ages 13-17		• Recommended starting dose for adolescents is lower than that for adults • Compared to patients from adult clinical trials, adolescents were likely to gain more weight, experience increased sedation, and have greater increases in total cholesterol, triglycerides, LDL cholesterol, prolactin and hepatic transaminase levels • Information on dosing, adverse reactions, pharmacokinetics, clinical studies				
62.	12/2/2009	Seroquel	quetiapine	Treatment of schizophrenia in adolescents 13 to 17 years of age and the treatment of bipolar mania in children and adolescents 10 to 17 years of age	Labeling	• Extended schizophrenia indication from adults to adolescents 13–17 years of age; extended bipolar mania indication from adults to children and adolescents 10-17 years of age • Safety and effectiveness in children < 13 years of age with schizophrenia have not been established; safety and effectiveness in children < 10 years of age with bipolar mania have not been established • Most adverse reactions in pediatric clinical trials were similar to those observed in adults and included somnolence, dizziness, fatigue, increased appetite, nausea, vomiting, dry mouth, tachycardia, and weight increase. However, increases in blood pressure and potentially clinically significant increases in heart rate (> 110 bpm) occurred in children and adolescents and did not occur in adults. • Information on dosing, adverse reactions, pharmacokinetics, and clinical studies	B, P	AstraZeneca	1/23/2009	
63.	12/1/2009	Patanase	olopatadine	Seasonal allergic rhinitis	Labeling	• Expanded age range down to 6 years; previously approved for use in 12 years and older • Safety and effectiveness have not been established in < 6 years of age • The incidence of epistaxis (nosebleed) was higher in children 6 -11 years of age compared to the adult and adolescent population • Information on clinical trials, adverse reactions, and new one spray per nostril twice daily dosing in 6-11 years	B, P	Alcon	8/12/2009	
64.	11/19/2009	Abilify	aripiprazole	Irritability associated with autistic disorder	Labeling	• Safety and effectiveness in pediatric patients demonstrating irritability associated with autistic disorder were established in two placebo-controlled clinical trials in pediatric patients 6 - 17 years of age • Most common adverse reactions observed in pediatric clinical trials in patients with autistic disorder included sedation, fatigue, vomiting, somnolence, tremor, pyrexia, drooling, decreased appetite, salivary hypersecretion, extrapyramidal disorder, and lethargy. Fatigue was a possible dose-response adverse reaction. • Information on dosing, adverse reactions, and clinical studies	P	Otsuka	NA	
65.	11/12/2009	Protonix	pantoprazole	GERD	Labeling	• Extended indication from adults to pediatric patients 5 years of age and older • Use in pediatric patients 1 to 16 years of age is supported by	B, P	Wyeth	2/17/2009	

	Labeling Date♦	Trade Name	Generic or Proper (Biologics●) Name	Indication(s) Studied	Product Labeling	Labeling Changes	BPCA (B)/ PREA (P)/ Rule (R)	Sponsor	PE Granted Date	N N P S
						extrapolation from studies in adults, and safety, efficacy and PK studies performed in pediatric patients • There is no age-appropriate formulation available for patients less than 5 years of age • Effectiveness was not demonstrated in a clinical trial of patients 1 month to 11 months of age with symptomatic GERD • Safety and effectiveness for pediatric uses other than EE have not been established • Information on adverse reactions, pharmacokinetics, and clinical studies				
66.	11/10/2009	AFLURIA	Influenza Virus Vaccine●	Active immunization for the prevention of influenza disease caused by virus types A and B contained in the vaccine	Package Insert	See Package Insert for new information on biologics	P	CSL Limited	NA	
67.	11/6/2009	Retrovir	zidovudine	Treatment of HIV-1 infection in combination with other antiretroviral agents	Labeling	• Provided dosing recommendations for patients 4 weeks to < 6 weeks of age and weighing 4 kg to < 9 kg	P	GlaxoSmith Kline	NA	✓
68.	10/23/2009	Focalin XR	dexmethylphenidate	ADHD	Labeling	• Revised maximum daily dosing due to dose-response studies. Doses above 30 mg/day in pediatrics and 40 mg/day in adults have not been studied and are not recommended • Dosing should be individualized to patient needs and response. • There was no clear benefit of the higher doses compared to the lower doses. Adverse events and discontinuations were dose-related. • New dosing regimen; new dosage strength (30 mg capsule)	P	Novartis	NA	
69.	10/22/2009	Atacand	candesartan	Hypertension	Labeling	• Expanded indication from adults to pediatric patients 1 to < 17 years of age. • Children < 1 year must not receive candesartan. Administering drugs that act directly on the renin-angiotensin system can have effects on the development of immature kidneys • Children with glomerular filtration rate < 30ml/min/1.73m2 should not receive candesartan. • In clinical trials, 4 of 233 children experienced worsening renal disease • Information on preparation of an oral suspension, dosing and administration, adverse events, pharmacokinetics, and clinical trials	B	AstraZeneca	7/20/2009	

	Labeling Date♦	Trade Name	Generic or Proper (Biologics●) Name	Indication(s) Studied	Product Labeling	Labeling Changes	BPCA (B)/ PREA (P)/ Rule (R)	Sponsor	PE Granted Date	N N P S
70.	10/19/2009	Fluarix	Influenza Virus Vaccine●	Active immunization for the prevention of influenza disease caused by virus types A and B contained in the vaccine	Package Insert	See Package Insert for new information on biologics	P	GlaxoSmith Kline	NA	
71.	10/16/2009	CERVARIX	Human Papillomavirus Bivalent (Types 16 and 18) Vaccine, Recombinant●	Prevention of genital warts caused by HPV 16 and 18	Package Insert	See Package Insert for new information on biologics	P	Merck	NA	
72.	10/16/2009	GARDASIL	Human Papillomavirus Quadrivalent (Types 6, 11, 16, 18) Vaccine, Recombinant●	Prevention of genital warts caused by HPV 6 and 11	Package Insert	See Package Insert for new information on biologics	P	Merck	NA	✓
73.	10/15/2009	Crestor	rosuvastatin	Heterozygous familial hypercholesterolemia	Labeling	• New indication in adolescent boys and girls (at least one year post-menarche) 10-17 years with heterozygous familial hypercholesterolemia • Has not been studied in children < 10 years or in pre-menarchal girls • Information on dose, adverse events and clinical studies	B, P	AstraZeneca	7/7/2009	
74.	10/2/2009	Welchol	colesevelam	Heterozygous familial hypercholesterolemia	Labeling	• New indication for use as monotherapy or with a statin in boys and postmenarchal girls 10-17 years with heterozygous familial hypercholesterolemia • Has not been studied in children < 10 years or in pre-menarchal girls • Information on dose, adverse events and clinical studies	B, P	Daiichi Sankyo	2/17/2009	
75.	10/1/2009	Mirena	levonorgestrel-releasing intrauterine system	Treatment of heavy menstrual bleeding for women using intrauterine contraception	Labeling	• New indication for the treatment of heavy menstrual bleeding for women who choose to use intrauterine contraception • Use before menarche is not indicated	P	Berlex	NA	✓
76.	9/18/2009	AndroGel	testosterone	Use in adolescent boys with delayed puberty	Labeling	• New safety information added to labeling including a Boxed Warning, and revisions to the Warnings and Precautions, Adverse Reactions, and Patient Counseling sections on the risk of virilization from secondary exposure of children to testosterone due to drug transfer from unwashed or uncovered application skin sites of adult males using testosterone gel products	B	Unimed	8/22/2007	✓

	Labeling Date♦	Trade Name	Generic or Proper (Biologics●) Name	Indication(s) Studied	Product Labeling	Labeling Changes	BPCA (B)/ PREA (P)/ Rule (R)	Sponsor	PE Granted Date	N N P S
						• Safety and efficacy have not been established in males < 18 years				
77.	9/8/2009	Bepreve Ophthalmic Solution	bepotastine besilate	Ocular itching associated with allergic conjunctivitis	Labeling	• Efficacy in pediatric patients 2 years to < 10 years based on clinical trials conducted in pediatric patients > 10 years and from adults • Safety and efficacy have not been established in pediatric patients < 2 years • New drug	P	Ista Pharmaceuticals	NA	
78.	9/2/2009	Intuniv	guanfacine	ADHD	Labeling	• Efficacy established in 2 controlled clinical trials in children 6-17 years • Safety and efficacy in pediatric patients< 6 years have not been established • In clinical trials, there were dose and exposure-related risks for adverse events (AEs) including hypotension, bradycardia, and sedative events. Somnolence and sedation were reported in 38% on guanfacine vs. 12% on placebo in children and adolescents with ADHD, especially during initial use • Information on dosing, clinical trials, and AEs • New dosage form	P	Shire	NA	
79.	8/31/2009	Astepro Nasal Spray	azelastine hydrochloride	Seasonal and perennial allergic rhinitis in patients 12 years of age and older.	Labeling	• Safety and efficacy for the treatment of seasonal and perennial allergic rhinitis were evaluated in 7 controlled clinical trials in patients 12 years and older • Information on clinical trials, dosing, and adverse events (AEs) • New indication (PAR) and dosing regimen	P	Meda	NA	
80.	8/28/2009	Valcyte	valganciclovir	Prevention of cytomegalovirus (CMV) disease in pediatric kidney and heart transplant patients ≥ 4 months of age	Labeling	• Use in pediatric patients ≥ 4 months is based on efficacy data from a study in adults and PK, safety, and efficacy data from an open-label trial in pediatric solid organ transplant recipients at risk for developing CMV disease • The efficacy and safety have not been established in children for: 1. Prevention of CMV disease in liver transplant patients 2. Prevention of CMV disease in solid organ transplants other than those indicated 3. Prevention of CMV disease in pediatric solid organ transplant patients < 4 months of age 4. Treatment of congenital CMV disease • Adverse events (AEs) similar to adult patients, however, certain Aes including upper respiratory tract infection, pyrexia, nasopharyngitis, anemia, and neutropenia were reported more frequently in pediatric patients • Information on dosing, PK, and clinical study	B, P	Roche	7/24/2008	

	Labeling Date♦	Trade Name	Generic or Proper (Biologics●) Name	Indication(s) Studied	Product Labeling	Labeling Changes	BPCA (B)/ PREA (P)/ Rule (R)	Sponsor	PE Granted Date	N N P S
						• New dosage form				
81.	8/27/2009	Zenpep	pancrelipase	Exocrine pancreatic insufficiency due to cystic fibrosis	Labeling	• Safety and efficacy assessed in 2 studies which included pediatric patients ages 1-17 years • Safety and efficacy for use in all pediatric age groups based on information from the literature and clinical experience with different formulations of pancrelipase with the same active ingredient. • High doses of pancreatic enzyme products have been associated with fibrosing colonopathy and colonic strictures in children <12 years of age • AEs similar to adults • Capsule should be swallowed whole. For infants or patients unable to swallow intact capsules, the contents may be sprinkled on soft acidic food such as applesauce • Information on dosing, and clinical studies • Not interchangeable with other pancrelipase products • New drug	P	Eurand	NA	
82.	8/21/2009	Xyzal	levocetirizine dihydrochloride	Seasonal allergic rhinitis (SAR) in children 2 years of age and older; perennial allergic rhinitis (PAR) and chronic idiopathic urticaria (CIU) for children 6 months of age and older	Labeling	• Expanded age range for CIU down to 6 months; previously approved for use in 12 years and older • Expanded age range for PAR down to 6 months; previously approved for use in 6 years and older • Expanded age range for SAR down to 2 years; previously approved for use in 6 years and older • Pediatric use is supported by evidence from studies in adults with additional safety and PK data in pediatrics • Patient population altered	B, P	UCB	8/25/2009	
83.	8/19/2009	HIBERIX	Haemophilus b Conjugate Vaccine (Tetanus Toxoid Conjugate) ●	Active immunization as a booster dose for the prevention of invasive disease caused by *Haemophilus influenzae* type b	Package Insert	See Package Insert for new information on biologics	P	GlaxoSmith Kline	NA	
84.	7/31/2009	Xerese	acyclovir/ hydrocortisone	Recurrent herpes labialis (cold sores) in 12 years of age and older	Labeling	• Use in adolescents ≥12 years is supported by evidence from studies in adults with additional safety data in adolescents ≥12 years • Safety and effectiveness in pediatric patients < 12 years have not been established	P	Medivir	NA	

	Labeling Date♦	Trade Name	Generic or Proper (Biologics●) Name	Indication(s) Studied	Product Labeling	Labeling Changes	BPCA (B)/ PREA (P)/ Rule (R)	Sponsor	PE Granted Date	N N P S
						• Information on clinical studies, and adverse events • New drug				
85.	7/23/2009	Actonel	risedronate	Osteogenesis imperfecta	Labeling	• Safety and effectiveness have not been established in pediatric patients • In a 1 year double-blind, placebo controlled study of pediatric patients with osteogenesis imperfecta (OI), treatment with risedronate did not result in a reduction in the risk of fracture • Adverse events similar to those observed in adults except for an increased incidence in vomiting • Information on clinical study	B	Procter & Gamble	4/24/2009	
86.	7/10/2009	Plan B One Step	levonorgestrel	Emergency contraception - OTC in women 17 years and older; RX for women younger than age 17 years	Labeling	• New single dose 1.5 mg tablet • New dosage regimen	P	Duramed	NA	
87.	6/18/2009	Nexium	esomeprazole	Short-term treatment of GERD	Labeling	• Effectiveness was not demonstrated in a randomized, placebo-controlled study in neonates to < 1 year • Information on clinical study, PK/PD parameters	B, P	AstraZeneca	5/1/2009	
88.	5/29/2009	Lamictal XR	lamotrigine*	Adjunctive therapy for partial onset seizures in patients ≥13 years of age	Labeling	• Extended release tablets are indicated as adjunctive therapy for partial onset seizures with or without secondary generalization in patients ≥13 years • Safety and effectiveness of extended release tablets for any use in patients below the age of 13 have not been established • Information on adverse event profile, and clinical studies • New dosage form	P	GlaxoSmith Kline	NA	
89.	5/28/2009	Besivance	besifloxacin ophthalmic suspension	Treatment of bacterial conjunctivitis	Labeling	• Efficacy in pediatric patients 1 year and older has been demonstrated in controlled clinical trials • Safety and effectiveness in infants < 1 year of age have not been established • There is no evidence that the ophthalmic administration of quinolones has any effect on weight bearing joints • Information on AE profile and clinical study • New drug	P	Bausch & Lomb	NA	
90.	5/8/2009	Lamictal	lamotrigine	Adjunctive treatment for partial	Labeling	• Safety and effectiveness as adjunctive treatment for partial seizures were not demonstrated in a small randomized, double-blind, placebo-controlled, withdrawal study in pediatric patients 1 - 24 months	B	GlaxoSmith Kline	2/14/2007	

	Labeling Date♦	Trade Name	Generic or Proper (Biologics●) Name	Indication(s) Studied	Product Labeling	Labeling Changes	BPCA (B)/ PREA (P)/ Rule (R)	Sponsor	PE Granted Date	N N P S
				seizures in pediatric patients 1 – 24 months		• Immediate release tablets were associated with an increased risk for infectious adverse reactions including bronchiolitis, bronchitis, ear infection, eye infection, otitis externa, pharyngitis, urinary tract infection, and viral infection (Lamictal 37%, Placebo 5%), and respiratory adverse reactions including nasal congestion, cough, and apnea. (Lamictal 26%, Placebo 5%)				
91.	5/1/2009	Cetraxal	ciprofloxacin otic solution	Treatment of acute otitis externa due to susceptible isolates of Pseudomonas aeruginosa or Staphylococcus aureus	Labeling	• Efficacy in pediatric patients 1 year and older has been demonstrated in controlled clinical trials • Safety and effectiveness in infants < 1 year have not been established • There is no evidence that the otic administration of quinolones has any effect on weight bearing joints • Information on AE profile and clinical study • New dosage form	P	Salvat	NA	
92.	4/30/2009	Axert	almotriptan	Acute treatment of pediatric migraine in adolescent patients age 12-17 years	Labeling	• Safety and effectiveness established in patients 12 – 17 years. Efficacy on migraine associated symptoms (nausea, photophobia and phonophobia) was not established. • Safety and effectiveness in pediatric patients < 12 years have not been established • The most common adverse events were dizziness, somnolence, headache, paresthesia, nausea and vomiting. Safety and tolerability similar to adults. • Information on dosing, adverse events, PK parameters, clinical study • Patient population altered	B	Ortho-McNeil	1/13/2009	
93.	4/30/2009	Creon	pancrelipase	Exocrine pancreatic insufficiency due to cystic fibrosis or other conditions	Labeling	• Safety and efficacy assessed in a study that included patients 12-18 years • Safety and efficacy for use in all pediatric age groups based on information from the literature and clinical experience with different formulations of pancrelipase containing the same active ingredient. • High doses of pancreatic enzyme products have been associated with fibrosing colonopathy in children <12 years of age • AEs similar to adults • Capsule should be swallowed whole. For infants or patients unable to swallow intact capsules, the contents may be sprinkled on soft acidic food such as applesauce • Information on dosing and clinical study • Not interchangeable with other pancrelipase products • New drug	P	Solvey	NA	
94.	4/14/2009	Suprane	desflurane	Safety study of 2 agents used for maintenance	Labeling	• Postmarketing Reports subsection added to the Adverse Events section of labeling, including reports of cardiac disorders. • Postmarketing reports are voluntary; it is not possible to estimate	B	Baxter	9/13/2006	✓

	Labeling Date♦	Trade Name	Generic or Proper (Biologics●) Name	Indication(s) Studied	Product Labeling	Labeling Changes	BPCA (B)/ PREA (P)/ Rule (R)	Sponsor	PE Granted Date	N N P S
				of anesthesia in non-intubated patients		frequency or causality to drug exposure.				
95.	4/9/2009	Ulesfia Lotion, 5%	benzyl alcohol	Treatment of head lice	Labeling	• Safety and effectiveness established in pediatric patients 6 months and older • Safety in pediatric patients < 6 months has not been established. • Not recommended in pediatric patients < 6 months due to potential for increased systemic absorption • Neonates are at risk of gasping syndrome due to benzyl alcohol • Adverse events similar to those observed in adults • Information on dosing and administration, warnings and precautions, adverse events, PK parameters, and clinical studies • New drug	P	Sciele Pharma Inc	NA	
96.	3/19/2009	Lexapro	escitalopram oxalate	Major depressive disorder in adolescents	Labeling	• Safety and effectiveness have been established in adolescents 12 to 17 years for the treatment of MDD. Maintenance efficacy is supported from extrapolation of data from adult studies along with comparisons with racemic citalopram pharmacokinetic parameters in adults and adolescents. • Safety and effectiveness have not been established in pediatric patients <12 years with MDD • Safety and effectiveness have not been established in pediatric patients less than 18 years of age with Generalized Anxiety Disorder • Adverse events generally similar to those observed in adults • Information on dosing, adverse events, PK parameters, and clinical studies • Patient population altered	B	Forest Laboratories	7/12/2002	
97.	12/19/2008	Casodex	bicalutamide	Gonadotropin-independent precocious puberty in boys with familial male-limited precocious puberty (testotoxicosis)	Labeling	• Safety and effectiveness have not been established in pediatric patients • Bicalutamide was studied in combination with anastrozole in an open-label, non-comparative, multi-center study that assessed the efficacy and safety of this combination regimen over 12 months in the treatment of testotoxicosis in patients ≥2 years • Of the 14 patients exposed to study treatment, 13 had at least one adverse event. Adverse reactions considered possibly related to bicalutamide included gynecomastia (43%), central precocious puberty (14%), breast tenderness (14%), breast pain (7%), asthenia (7%), increased alanine aminotransferase (7%), increased aspartate aminotransferase (7%), and musculoskeletal chest pain (7%). Headache was the only adverse reaction considered possibly related to anastrozole • Information on clinical studies, AEs, and PK parameters	B	AstraZeneca	9/19/2008	
98.	12/19/2008	Ziagen	abacavir	HIV infection	Labeling	• Provided new scored tablet for use in pediatric patients weighing >14	B, P	GlaxoSmith Kline	12/14/1998	✓

	Labeling Date♦	Trade Name	Generic or Proper (Biologics●) Name	Indication(s) Studied	Product Labeling	Labeling Changes	BPCA (B)/ PREA (P)/ Rule (R)	Sponsor	PE Granted Date	N N P S
						kg who can swallow tablets • New dosing regimen				
99.	12/18/2008	Prezista	darunavir	Treatment of HIV infection in pediatric patients 6 years and older when co-administered with ritonavir (Prezista/rtv), and with other antiretroviral agents	Labeling	• Extended indication from adults to pediatric patients 6 years and older • Safety and effectiveness in pediatric patients 3 to < 6 years of age have not been established • Do not administer in pediatric patients below 3 years of age • Do not administer Prezista/rtv once daily in pediatric patients • Dosing for patients 6 to < 18 years and weighing at least 44 lbs (20 kg) is based on body weight not to exceed adult dose • AE similar to those seen in adults • Information on dose, Aes, PK parameters, lab abnormalities, and clinical study	B, P	Tibotec	NA	
100.	12/17/2008	Epiduo	adapalene and benzoyl peroxide	Topical treatment of acne vulgaris in patients 12 years of age and older	Labeling	• Safety and effectiveness established in patients 12 years of age and older • Safety and effectiveness in pediatric patients under the age of 12 have not been established • New drug	P	Galderma	NA	
101.	12/11/2008	PegIntron	Peginterferon alfa-2b	Co-administered with ritonavir to treat chronic hepatitis C in patients 3 years of age and older with compensated liver disease previously untreated with interferon alpha	Labeling	• Safety and efficacy established in pediatric patients 3–17 years of age • Safety and effectiveness in patients < 3 years have not been established. • Dosing for pediatric patients is determined by body surface area for peginterferon alfa-2b and by body weight for ritonavir • An open-label study in patients 3 - 17 years showed weight and height gain of pediatric patients treated with combination therapy lags behind that predicted by population data while on treatment. • Adverse events similar to those observed in adults. Most common pediatric adverse events were pyrexia, headache, neutropenia, fatigue, anorexia, injection site erythema, vomiting • Information on PK parameters, and clinical study • New indication	P	Schering	NA	
102.	12/5/2008	Arimidex	anastrozole	Male pubertal patients with gynecomastia and female pediatric patients with McCune-Albright syndrome with progressive precocious	Labeling	• Efficacy has not been demonstrated in clinical studies of anastrozole in the treatment of pubertal gynecomastia in adolescent boys 11-18 years and in the treatment of precocious puberty in girls with McCune-Albright Syndrome 2 to < 10 years • Information on clinical studies, AEs, and PK parameters	B	AstraZeneca	11/14/2007	

	Labeling Date♦	Trade Name	Generic or Proper (Biologics●) Name	Indication(s) Studied	Product Labeling	Labeling Changes	BPCA (B)/ PREA (P)/ Rule (R)	Sponsor	PE Granted Date	N N P S
				puberty						
103.	11/14/2008	Neulasta	Pefilgrastim	Sarcoma	Labeling	• Safety and effectiveness in pediatric patients have not been established • Safety and PK were studied in 37 pediatric patients with sarcoma • Information added to Pediatric Use	P	Amgen	NA	
104.	10/28/2008	Prevacid	lansoprazole	Short-term treatment of symptomatic GERD and erosive Esophagitis	Labeling	• Expanded age range to include patients 12 -17 years of age; previously labeled only in pediatric patients 1-11 years of age • Safety and effectiveness in pediatric patients <1 year of age have not been established • Information on dose, PK parameters, and AE profile	B, P	Takeda	7/15/2008	
105.	10/24/2008	Apidra	insulin glulisine recombinant	Diabetes Mellitus	Labeling	• Extended indication from adults to pediatric patients 4 years and older with type 1 diabetes • Has not been studied in pediatric patients less than 4 years with type 1 diabetes and in pediatric patients with type 2 diabetes • Pediatric patients had a higher incidence of severe symptomatic hypoglycemia compared to adults in the clinical study • New indication	P	Sanofi-Aventis	NA	
106.	10/21/2008	Acanya Gel	clindamycin/ benzoyl peroxide combination	Acne vulgaris in patients 12 years of age and older	Labeling	• Safety and effectiveness established in 2 clinical studies in patients 12 years of age and older • Safety and effectiveness in pediatric patients under the age of 12 have not been evaluated • New drug	P	Dow	NA	
107.	10/14/2008	Zomig Nasal Spray	zolmitriptan	Migraine	Labeling	• Safety and effectiveness have not been established in pediatric patients less than18 years of age. • A single, multi-center, double-blind randomized placebo-controlled study failed to demonstrate efficacy in pediatric patients ages 12 -17 years for the acute treatment of migraine headaches • Adverse events similar to those observed in adults.	B, P	AstraZeneca	12/18/2003	
108.	10/10/2008	Kogenate FS	Antihemophilic Factor (Recombinant)●	Routine prophylaxis to reduce the frequency of bleeding episodes and the risk of joint damage in children with hemophilia A with no pre-existing joint damage	Package Insert	See Package Insert for new information on biologics	P	Bayer	NA	

	Labeling Date♦	Trade Name	Generic or Proper (Biologics●) Name	Indication(s) Studied	Product Labeling	Labeling Changes	BPCA (B)/ PREA (P)/ Rule (R)	Sponsor	PE Granted Date	N N P S
109.	10/8/2008	Zmax Oral Susp	azithromycin	Community-Acquired Pneumonia	Labeling	• Safety and effectiveness established in pediatric patients 6 months of age or older with community-acquired pneumonia. Use is supported by evidence from studies in adults with additional safety and PK data in pediatric patients • Safety and effectiveness in the treatment of pediatric patients < 6 months of age have not been established. • Safety and effectiveness in the treatment of pediatric patients with acute bacterial sinusitis have not been established • Information on dose, PK parameters, AE profile, lab abnormalities, and clinical studies • New indication	P	Pfizer	NA	✓
110.	10/07/2008	Akten Ophthalmic gel 3.5%	lidocaine hydrochloride	Ocular surface anesthesia during ophthalmologic procedures	Labeling	• Safety and efficacy extrapolated from studies in adults and older pediatric patients using different ophthalmic formulations of lidocaine. • New dosage form	P	Akorn	NA	✓
111.	9/29/2008	Videx EC	didanosine	HIV infection in >20 kg	Labeling	• Extended indication from adults to children weighing ≥20kg who can swallow capsules • Dosing is based on body weight not to exceed adult dose • Adverse events (AEs) are generally similar to those seen in adults • Information on dose, AEs, population PK analysis, lab abnormalities, and historical clinical studies	B, P	Bristol-Myers Squibb	8/13/2001	✓
112.	9/19/2008	Nasacort AQ	triamcinolone	Treatment of the nasal symptoms of seasonal and perennial allergic rhinitis in adults and children 2 years of age and older	Labeling	• Expands pediatric use, or age range, to include patients 2 to 5 years of age • Dosing and administration information provided • Not recommended for children under 2 years of age • An effect on adrenal function in children 2 to 5 years of age cannot be ruled out • Pharmacokinetics were evaluated in children 2 to 5 years of age • Safety and efficacy were evaluated in one clinical study involving pediatric patients 2 to 5 years old • Studies in children >6 months and less than 2 years of age were not performed due to safety concerns since controlled clinical studies have shown that intranasal corticosteroids may cause a reduction in growth velocity in pediatric patients.	P	Sanofi-Aventis	NA	
113.	9/19/2008	Retrovir syrup, capsules and tablets#	zidovudine	Used in combination with 18 other antiretroviral agents for the treatment of HIV-1 infection	Labeling	• Dosing and administration information provided to children 6 weeks to less than 18 years of age • Macrocytosis was reported in the majority of pediatric patients receiving Retrovir 180 mg/m2 every 6 hours in open-label studies • New dosing regimen	P	GlaxoSmith Kline	NA	✓

	Labeling Date♦	Trade Name	Generic or Proper (Biologics●) Name	Indication(s) Studied	Product Labeling	Labeling Changes	BPCA (B)/ PREA (P)/ Rule (R)	Sponsor	PE Granted Date	N N P S
114.	9/12/2008	GARDASIL	Human Papillomavirus Quadrivalent (Types 6, 11, 16, 18) Vaccine, Recombinant●	Prevention of vulvar and vaginal cancer caused by HPV types 16 and 18	Package Insert	See Package Insert for new information on biologics	P	Merck	NA	
115.	9/3/2008	Valtrex	valacyclovir	Chickenpox; active or at risk for herpes virus infection	Labeling	• New indication for treatment of chickenpox in pediatric patients 2 to <18 years based on single-dose pharmacokinetic and multiple-dose safety data from an open-label trial with valacyclovir and supported by safety and extrapolated efficacy data from 3 randomized, double-blind, placebo-controlled trials evaluating oral acyclovir in pediatric patients with chickenpox • The efficacy and safety of valacyclovir have not been established in pediatric patients: o <12 years of age with cold sores o <18 years of age with genital herpes o <18 years of age with herpes zoster o <2 years of age with chickenpox, o for suppressive therapy following neonatal HSV infection • Adverse events similar to that of adults • Information on PK parameters, AEs, clinical studies, and preparation of an extemporaneous formulation	B, P	GlaxoSmith Kline	2/26/2008	
116.	8/28/2008	Zemuron	rocuronium	Adjunct to general anesthesia	Labeling	• Expanded pediatric indication to include 0-17 years. Previously approved in ages 3 months – 14 years • Not recommended for rapid sequence intubation in pediatric patients • In clinical studies of rocuronium, onset time and clinical duration varied with dose, the age of the patient, and anesthetic technique • The overall analysis of ECG data in pediatric patients indicates that the concomitant use of rocuronium with general anesthetic agents can prolong the QTc interval • The time to maximum block for an intubating dose was shortest in infants and longest in neonates. The duration of clinical relaxation following an intubating dose is shortest in children > 2 years to 11 years and longest in infants • Additional information on dose, clinical studies, and PK/PD parameters	B, P	Organon USA	4/3/2008	
117.	8/14/2008	Zyprexa	olanzapine	schizophrenia; bipolar disorder		• Safety and effectiveness have not been established for patients less than 18 years of age • In an analysis of placebo-controlled olanzapine monotherapy studies of adolescent patients, including those with schizophrenia or bipolar disorder, olanzapine was associated with:	B	Lilly	1/10/2007	

	Labeling Date♦	Trade Name	Generic or Proper (Biologics●) Name	Indication(s) Studied	Product Labeling	Labeling Changes	BPCA (B)/ PREA (P)/ Rule (R)	Sponsor	PE Granted Date	N N P S
						o Hyperglycemia - a statistically significantly greater mean change in fasting glucose levels compared to placebo o Hyperlipidemia – statistically significant increases compared to placebo in fasting triglycerides, fasting total cholesterol and fasting LDL cholesterol o Weight gain – olanzapine treated patients gained an average of 4.6 kg, compared to an average of 0.3 kg in placebo-treated patients with a median exposure of 3 weeks; Average weight gain during long-term therapy was 7.4 kg				
118.	7/29/2008	Cancidas	caspofungin	Empirical therapy for presumed fungal infections in febrile, neutropenic patients; Candidemia and certain Candida infections; Esophageal Candidiasis; Invasive Aspergillosis in patients who are refractory to or intolerant of other therapies	Labeling	• Extended indication from adults to children 3 months and older based upon evidence from adequate and well-controlled studies in adults and PK data in pediatric patients and additional data from pediatric studies • The efficacy and safety have not been adequately studied in infants < 3 months • The ability of caspofungin to penetrate the blood-brain barrier and to treat patients with meningitis and endocarditis is unknown • Dosing should be based on the patient's body surface area. Maximum loading dose and daily maintenance dose should not exceed 70 mg • The safety profile in pediatrics is comparably to adults • Information on dose, Aes, PK parameters, clinical studies and infusion preparation instructions	B, P	Merck	4/15/2008	
119.	7/24/2008	Navstel Intraocular Irrigating Solution Sterile#	balanced salt ophthalmic solution with hypromellose, dextrose and glutathione	Use as an intraocular irrigating solution during surgical procedures involving perfusion of the eye	Labeling	• Safety and efficacy have been demonstrated in pediatric patients • New active ingredient	P	Alcon	NA	✓
120.	7/1/2008	Flovent HFA	fluticasone propionate	Asthma in < 4 years	Labeling	• Flovent HFA should be administered by the orally inhaled route only in patients 4 years and older. • Clinical studies were conducted in children with asthma 6 months to less than 4 years • Information added to Pediatric Use	P	GlaxoSmith Kline	NA	
121.	6/30/2008	Aciphex	rabeprazole	Gastroesophageal reflux in	Labeling	• Use in adolescent patients 12 years of age and older is supported by	B, P	Eisai Medical	NA	

	Labeling Date♦	Trade Name	Generic or Proper (Biologics●) Name	Indication(s) Studied	Product Labeling	Labeling Changes	BPCA (B)/ PREA (P)/ Rule (R)	Sponsor	PE Granted Date	N N P S
				adolescent patients 12 years of age and above		extrapolation of results from studies in adults and safety and PK studies performed in adolescent patients • Safety and effectiveness for GERD have not been established for pediatric patients <12 years of age • Safety and effectiveness for other uses have not been established in pediatric patients • Adverse events (AEs) similar to those seen in adults • Information on dose, AEs, clinical studies		Research		
122.	6/24/2008	KINRIX	Diphtheria and Tetanus Toxoids and Acellular Pertussis Adsorbed and Inactivated Poliovirus Vaccine●	Active immunization against diphtheria, tetanus, pertussis, & poliomyelitis as the fifth dose in the diphtheria, tetanus, and acellular pertussis (DTaP) vaccine series and the fourth dose in the inactivated poliovirus vaccine (IPV) series when previous DTaP vaccine doses have been with INFANRIX and/or PEDIARIX and for the first three doses and INFANRIX for the fourth dose	Package Insert	See Package Insert for new information on biologics	P	GlaxoSmith Kline Biologicals	NA	
123.	6/24/2008	Viramune Tablets 200 mg Viramune Oral Suspension 10	nevirapine	Use in combination with other antiretroviral agents for the treatment of HIV-1 infection	Labeling	• Dosing information provided for children ages >15 days to <16 years old • Safety was evaluated in children 2 weeks and older in 5 clinical trials and important adverse events (all causality) include rash (21%), neutropenia (8.9%), anemia (7.3%) and hepatotoxicity (2.4%) • Safety, pharmacokinetics, and virologic and immunologic responses have been evaluated in HIV-infected pediatric patients age 3 months to 18 years	P	Boehringer Ingelheim	NA	

	Labeling Date♦	Trade Name	Generic or Proper (Biologics●) Name	Indication(s) Studied	Product Labeling	Labeling Changes	BPCA (B)/ PREA (P)/ Rule (R)	Sponsor	PE Granted Date	N N P S
		mg/mL				• Safety and pharmacokinetics were evaluated in HIV-infected pediatric patients age 15 days to < 3 months • Efficacy was evaluated in one clinical study with children 3 months to 16 years of age • Post-marketing surveillance has shown anemia to be more commonly observed in children although development of anemia due to concomitant medication use cannot be ruled out • Potential drug interaction information is provided for children with respect to lopinavir/ritonavir • New dosing regimen				
124.	6/23/2008	Aptivus	tipranavir	Co-administered with ritonavir for combination antiretroviral in patients who are treatment-experienced and infected with HIV-1 strains resistant to more than one protease inhibitor	Labeling	• Extended indication from adults to children 2 years and older • The risk-benefit has not been established in patients <2 years of age • Dosing is based on body weight or body surface area not to exceed adult dose • Aes are generally similar to those seen in adults however, rash was more frequent in pediatric patients than in adults; The frequency of rash through 48 weeks of treatment was 21%. Most rashes were mild and 5% were moderate. Overall 3% interrupted treatment due to rash • Information on dose, Aes, PK parameters, lab abnormalities, and clinical study	B, P	Boehringer Ingelheim	3/7/2008	
125.	6/20/2008	Kaletra	lopinavir/ ritonavir	Use in combination with other antiretroviral agents for HIV-1 infection	Labeling	• Extended indication from 6 months – 12 years to 14 days – 18 years • The safety, efficacy, and pharmacokinetic profiles in pediatric patients < 14 days have not been established • Dose should be calculated based on body weight or body surface area not to exceed adult dose • Because no data exists for dosage when administered with efavirenz, nevirapine, (fos)amprenavir, or nelfinavir, it is recommended that lopinavir/ ritonavir not be administered in combination with these drugs in patients < 6 months of age • Infants <6 months of age generally had lower lopinavir AUC12 than children 6 months – 12 years of age • Information on dose, PK parameters, clinical studies, and AEs	B, P	Abbott	3/7/2008	
126.	6/20/2008	Pentacel	Diphtheria And Tetanus Toxoids and Acellular Pertussis Adsorbed, Inactivated Poliovirus and Haemophilus B	Active immunization against diphtheria, tetanus, pertussis, poliomyelitis and invasive	Package Insert	See Package Insert for new information on biologics	P	Sanofi Pasteur	NA	

	Labeling Date♦	Trade Name	Generic or Proper (Biologics●) Name	Indication(s) Studied	Product Labeling	Labeling Changes	BPCA (B)/ PREA (P)/ Rule (R)	Sponsor	PE Granted Date	N N P S
			Conjugate (Tetanus Toxoid Conjugate) Vaccine●	disease due to *Haemophilus influenzae* type b						
127.	6/5/2008	Zetia and Vytorin	ezetimibe and ezetimibe/ simvastatin	Heterozygous familial hypercholesterolemia as an adjunct to diet	Labeling	• The effects of ezetimibe co-administered with simvastatin compared to simvastatin monotherapy have been evaluated in adolescent boys and girls with heterozygous familial hypercholesterolemia (HeFH)	B, P	MSP Singapore	2/14/2008	
128.	5/9/2008	OraVerse Injection 0.4 mg (0.235 mg/mL)	phentolamine mesylate	Reversal of soft-tissue anesthesia, i.e., anesthesia of the lip and tongue, and the associated functional deficits resulting from an intraoral submucosal injection of a local anesthetic containing a vasoconstrictor		• Use in children less than 6 years of age or weighing less than 15 kg (33 lbs) is not recommended • Dosing information provided for children weighing 15 to 30 kg (66 lbs) • Safety and efficacy were established in 2 clinical trials in children 12 to 17 years old, one trial in children ages 6 to 11 years, as well as adult studies • Safety has been evaluated in pediatric patients under the age of 6 years but not efficacy • Pharmacokinetics have been evaluated in children weighing 15 kg or more • New indication	P	Novalar Pharmaceuticals, Inc.	NA	
129.	5/8/2008	Desmopressin acetate Tablets, 0.1 mg and 0.2 mg	desmopressin acetate	Determine the capacity of the kidney to concentrate urine in pediatric patients (Renal Concentration Capacity Test or RCCT) and management of primary nocturnal enuresis (PNE)		• Efficacy in RCCT was evaluated in a single trial with children 3 to 18 years old • Three studies evaluated efficacy in children 5 to 17 years old with PNE; an additional study evaluated efficacy in adolescents 12 to 17 years old • Fluid intake should be adjusted downward in children to decrease the potential occurrence of water intoxication and hyponatremia • Dosing information provided for children 3 to 18 years old for RCCT • Dosing information provided for pediatric patients 6 years of age and older with PNE • Tablet dosage and administration information provided for children with central diabetes insipidus • Pharmacokinetics and pharmacodynamics were evaluated in children • New indications and dosing regimen	P	Ferring	NA	
130.	5/5/2008	Argatroban	argatroban	Heparin-Induced Thrombocytop	Labeling	• Safety and effectiveness, including the appropriate anticoagulation goals and duration of therapy, have not been established in pediatric patients	B, P	Encysive	NA	

	Labeling Date♦	Trade Name	Generic or Proper (Biologics●) Name	Indication(s) Studied	Product Labeling	Labeling Changes	BPCA (B)/ PREA (P)/ Rule (R)	Sponsor	PE Granted Date	N N P S
				enia (HIT) or HIT with Thrombosis		• Population PK/PD analysis of sparse data in 15 seriously ill pediatric patients ages <6 months – 16 years diagnosed with HIT or suspected HIT requiring an alternative to heparin anticoagulation showed clearance in pediatric patients was 50% lower compared to healthy adults and led to dose recommendations • Information on dose, AEs and PK				
131.	5/5/2008	Levaquin Tablets, 250 mg, 500 mg, and 750 mg# Levaquin Oral Solution, 25 mg/mL# Levaquin Injection and Levaquin Injection, 5 mg/mL#	levofloxacin levofloxacin in 5% dextrose injection	Reduce the incidence or progression of disease following exposure to aerosolized Bacillus anthracis (inhalational anthrax post-exposure)		• New indication • Dosing information provided for children less than and greater than 50 kg • Efficacy is based on plasma concentrations achieved in humans, a surrogate endpoint reasonably likely to predict clinical benefit, and animal studies were used to evaluate survival; the product has not been tested in humans for the post-exposure prevention of inhalation anthrax • Safety in pediatric patients treated for more than 14 days has not been studied • Long-term safety data, including effects on cartilage, following administration in pediatric patients is limited • Due to possible side effects, use is not recommended for pediatric patients except in the prevention of anthrax after inhalational exposure • Pharmacokinetics were investigated in pediatric patients 6 months to 16 years old	P	Ortho-McNeil-Janssen Pharmaceutical, Inc.	NA	✓
132.	4/30/2008	Cardiolite	technetium tc99m sestamibi	Medical imaging in Kawasaki disease	Labeling	• Safety and effectiveness have not been established in the pediatric population • No evidence of diagnostic efficacy or clinical utility of scan was found in 3 clinical studies of children and adolescents with Kawasaki disease • A study of 445 pediatric patients failed to demonstrate the predictive value of Cardiolite rest and stress myocardial perfusion imaging to define children with Kawasaki disease at risk of developing cardiac events 6 months after receiving Cardiolite; only 3cardiac events were observed. In all 3 cases, the scan was negative • Adverse events similar to that of adults • Information on dose, PK, and clinical studies	B, P	Lantheus Medical Imaging	1/11/2008	
133.	4/15/2008	Patanase Nasal Spray	olopatadine hydrochloride	Relief of symptoms of seasonal allergic rhinitis (SAR) in patients 12 years of age and older	Labeling	• Safety and effectiveness in children below the age of 12 years have not been established • Symptoms of antihistamine overdose in children may initially include agitation and restlessness followed by drowsiness • Efficacy and safety were evaluated in 3 clinical trials of 2 weeks duration in adult and adolescent patients, 12 years of age and older, with symptoms of SAR	P	Alcon Research, Ltd.	NA	

	Labeling Date♦	Trade Name	Generic or Proper (Biologics●) Name	Indication(s) Studied	Product Labeling	Labeling Changes	BPCA (B)/ PREA (P)/ Rule (R)	Sponsor	PE Granted Date	N N P S
						• Dosage and administration information provided for children 12 years and older • New indication, dosage form, dosing regimen, and route of administration				
134.	4/7/2008	Orencia	abatacept	Moderate to severe polyarticular juvenile idiopathic arthritis		• Indicated for reducing signs and symptoms in pediatric patients with moderately to severely active polyarticular juvenile idiopathic arthritis (JIA) ages 6 years and older. • The safety and effectiveness in pediatric patients < 6 years of age and in pediatric patients for uses other than JIA have not been established • Abatacept was studied in 190 patients 6 - 17 years with polyarticular JIA. • AEs were generally similar to those seen in adults. Overall frequency of adverse events in the 4-month, lead-in, open-label period of the study was 70%; infections occurred at a frequency of 36%. A total of 6 serious adverse events were reported during the initial 4 months of treatment with abatacept. • Information on dosing, PK, immunogenicity, immunization needs, AEs, and clinical study • New indication	P	Bristol-Myers Squibb	NA	
135.	4/3/2008	ROTARIX	Rotavirus Vaccine, Live, Oral●	Prevention of rotavirus gastroenteritis caused by G1 and non-G1 types (G3, G4, and G9)	Package Insert	See Package Insert for new information on biologics	P	GlaxoSmith Kline Biolgocials	NA	
136.	3/31/2008	Lancôme UV Expert 40 La Roche-Posay Anthelios 40 Vichy Capital Soleil 40	avobenzone, ecamsule, octocrylene, titanium dioxide cream	Sunscreen OTC		• Effectiveness extrapolated from adult studies • Safety studies included pediatric patients 6 months of age and older • Age range based on standards established in over-the –counter monograph for sunscreens • New active ingredient •	P	L'Oreal USA	NA	
137.	3/26/2008	Ventolin HFA	albuterol	Treatment of symptoms of bronchospasm associated with obstructive airway	Labeling	• Safety and effectiveness of albuterol administered with or without a spacer device in children < 4 years of age has not been demonstrated • 3 randomized, double-blind, placebo-controlled studies in 250 children < 4 years, in which efficacy was not demonstrated, suggest that either the optimal dose has not been defined in this age-group or the drug is not effective in this age-group	B	GlaxoSmith Kline	8/27/2008	

	Labeling Date♦	Trade Name	Generic or Proper (Biologics●) Name	Indication(s) Studied	Product Labeling	Labeling Changes	BPCA (B)/ PREA (P)/ Rule (R)	Sponsor	PE Granted Date	N N P S
				disease		• Information on clinical studies				
138.	3/25/2008	Reyataz	atazanavir	HIV in 6 years and older	Labeling	• Extended indication from adults to children 6 years and older • The safety, activity, and pharmacokinetic profiles in pediatric patients ages 3 months to < 6 years have not been established. Atazanavir should not be administered to pediatric patients below the age of 3 months due to the risk of kernicterus • Dosing is based on body weight or body surface area not to exceed adult dose • Adverse events (AEs) are generally similar to those seen in adults • Information on dose, AEs, PK parameters, lab abnormalities, and clinical study	B, P	Bristol-Myers Squibb	NA	
139.	3/24/2008	Depakote ER Depakote Sprinkles	divalproex disodium	Pediatric Bipolar Disorder; Prophylaxis of Migraine	Labeling	• Efficacy was not established in a double-blind, placebo controlled study of patients 10-17 years conducted to evaluate efficacy in the treatment of pediatric bipolar disorder • Efficacy was not established in a double-blind, placebo-controlled study of patients 12 – 17 years conducted to evaluate the efficacy in the prophylaxis of migraine • The safety and tolerability was similar to adults in 5 long-term safety studies • Additional information on clinical studies, AE profile in Depakote ER labeling	B, P	Abbott	12/14/2007	
140.	3/20/2008	Prilosec	omeprazole	Maintenance healing of erosive esophagitis	Labeling	• Efficacy was extrapolated from adults and older children to 1 to 2 year olds and supported with an open-label trial • Unique adverse reactions in pediatric patients included increased respiratory system adverse events and fever. • Safety and effectiveness in children less than 1 year of age have not been established • Dosing and administration information provided for patients 1 year and older weighing at least 5 kg. • New dosage form	B, P	AstraZeneca	NA	
141.	3/20/2008	Zometa	zoledronic acid	Severe osteogenesis imperfecta	Labeling	• Zoledronic acid is not indicated for use in children • Safety and effectiveness was studied in 152 pediatric patients with severe osteogenesis imperfecta aged 1 - 17 years. At one year, increases in BMD were observed in the zoledronic acid treatment group but the changes did not necessarily correlate with the risk for fracture or the incidence or severity of chronic bone pain • Information on PK, clinical study, and AE profile	B	Novartis	12/21/2007	
142.	3/19/2008	ARTISS	Fibrin Sealant (Human)●	To adhere autologous	Package Insert	See Package Insert for new information on biologics	P	Baxter	NA	

	Labeling Date♦	Trade Name	Generic or Proper (Biologics●) Name	Indication(s) Studied	Product Labeling	Labeling Changes	BPCA (B)/ PREA (P)/ Rule (R)	Sponsor	PE Granted Date	N N P S
				skin grafts to surgically prepared wound beds resulting from burns						
143.	3/14/2008	NovoLog	insulin aspart [rDNA origin] injection	Insulin analog indicated to improve glycemic control	Labeling	• Efficacy was demonstrated in a clinical study with pediatric patients ages 4 to 18 years using an external insulin pump • New dosing regimen	P	Novo Nordisk	NA	
144.	3/12/2008	DAPTACEL	Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine Adsorbed●	*Active immunization as a booster dose against diphtheria, tetanus & pertussis*	Package Insert	See Package Insert for new information on biologics	P	Sanofi Pasteur	NA	
145.	2/27/2008	Abilify	aripiprazole	Bipolar I Disorder	Labeling	• Extended treatment of acute Bipolar Disorder indication from adults to pediatrics 10–17 years • The efficacy for the maintenance treatment of Bipolar Disorder in the pediatric population has not been evaluated • The recommended target dose in Bipolar Disorder is 10 mg/day. • In the study of pediatric patients 10 – 17 years with Bipolar Mania, 4 common adverse reactions had a possible dose response relationship at 4 weeks; extrapyramidal disorder, somnolence, akathisia and salivary hypersecretion • Information on dose, AEs, clinical studies	B, P	Otsuka	11/14/2007	
146.	2/27/2008	Nexium	esomeprazole	Short-term treatment of GERD	Labeling	• Expanded age range to include pediatric patients 1-11 years. Previously approved in 12-17 years • Use in pediatric patients 1 to 17 years of age is supported by extrapolation from studies in adults, and safety and PK studies performed in pediatric and adolescent patients • Safety and effectiveness in pediatric patients <1 year of age have not been established • Safety and effectiveness for other pediatric uses have not been established • Information on dose, treatment related adverse events (AEs), clinical study • New formulation	B	AstraZeneca	5/1/2009	
147.	2/21/2008	Humira	adalimumab	Treatment of juvenile idiopathic arthritis	Labeling	• Indicated for reducing signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis (JIA)in patients 4 years of age and older • Has not been studied in children <4 years of age; there are limited data on treatment in children with weight <15 kg	P	Abbott	NA	

	Labeling Date♦	Trade Name	Generic or Proper (Biologics●) Name	Indication(s) Studied	Product Labeling	Labeling Changes	BPCA (B)/ PREA (P)/ Rule (R)	Sponsor	PE Granted Date	N N P S
						• Safety and efficacy in pediatric patients for uses other than JIA have not been established • Adalimumab was studied in 171 patients 4 - 17 years with polyarticular JIA. • AEs were generally similar to those seen in adults. 45% of children experienced an infection while receiving adalimumab with or without concomitant MTX in the first 16 weeks of treatment. Serious infections were observed in 4% of patients within approximately 2 years of initiation of treatment • Information on dose, AEs, lab abnormalities, PK parameters, immunogenicity, immunization needs and clinical study • New indication				
148.	2/1/2008	Asmanex Twisthaler 110mcg inhalation powder	mometasone furoate	Maintenance treatment of asthma as prophylactic therapy in children 4 years of age and older		• Not indicated for relief of acute bronchospasm or in children less than 4 years of age • Clinical studies, including 52 week safety trial conducted in children 4 – 11 years of age • Pediatric dosing information provided • Child may not get the most benefit for 1 to 2 weeks or longer after starting treatment • New dosage form	P	Schering Corporation	NA	
149.	1/31/2008	Inspra	eplerenone	Hypertension	Labeling	• Effectiveness was not established in a study of 304 hypertensive pediatric patients 4 - 17 years; eplerenone, at doses up to 100 mg/ day, did not lower blood pressure effectively • Therefore, it has not been studied in hypertensive patients <4 years old • Eplerenone has not been studied in hypertensive patients < 4 years or in pediatric patients with heart failure • Adverse events similar to that of adults	B, P	Pfizer	10/24/2007	
150.	1/28/2008	Xyzal 0.5 mg/mL Oral Solution#	levocetirizine dihydrochloride	Relief of symptoms associated with seasonal and perennial allergic rhinitis (SAR and PAR) and treatment of uncomplicated skin manifestations of chronic idiopathic urticaria (CIU)	Labeling	• Dosing information provided • Studies waived in children less than 6 months of age with PAR and CIU • Waived in children less than 2 years of age with SAR • New dosage form pediatric	P	UCB	NA	✓

	Labeling Date♦	Trade Name	Generic or Proper (Biologics●) Name	Indication(s) Studied	Product Labeling	Labeling Changes	BPCA (B)/ PREA (P)/ Rule (R)	Sponsor	PE Granted Date	N N P S
151.	1/23/2008	Moxatag	amoxicillin	Use for tonsillitis and/or pharyngitis secondary to Streptococcus pyogenes patients 12 years of age and older	Labeling	• Safety and effectiveness in pediatric patients younger than 12 years have not been established • One clinical study evaluated safety and effectiveness in pediatric patients 12 years of age and older with no significant differences in treatment response or adverse reactions between adults and children • A prospective study of 51 children suggested that overdosages of less than 250 mg/kg are not associated with significant clinical symptoms and do not require gastric emptying • Waiver of studies in children ages 0 to less than two years because too few children have the disease • New dosage form	P	Middlebrook Pharmaceuticals	NA	
152.	1/17/2008	TamiFlu	oseltamivir	Safety information resulting from studies that established treatment of uncomplicated acute illness due to influenza infection in patients 1 year and older	Labeling	• Influenza can be associated with a variety of neurologic and behavioral symptoms which can include events such as hallucinations, delirium, and abnormal behavior, in some cases resulting in fatal outcomes. These events may occur in the setting of encephalitis or encephalopathy but can occur without obvious severe disease. • These events have been reported in patients receiving oseltamivir, primarily among pediatric patients, appear to be uncommon, and often had an abrupt onset and rapid resolution • If neuropsychiatric symptoms occur, the risks and benefits of continuing treatment should be evaluated for each patient	B	Roche	3/22/2004	✓
153.	1/10/2008	Alvesco Inhalation Aerosol, 80 mcg & 160 mcg	ciclesonide	Treatment of asthma in patients 12 years of age and older.	Labeling	• Not indicated for children under the age of 12 years • Five clinical studies evaluated safety in children 12 years of age and older • Safety and effectiveness have not been established in children under 12 years of age • Waiver of studies in children 0 to less than 6 months of age due to too few patients with the disease • New dosage form	P	Nycomed US Inc.	NA	
154.	1/2/2008	EVICEL	Fibrin Sealant (Human)●	Adjunct to hemostasis for use in patients undergoing surgery, when control of bleeding by standard surgical techniques is ineffective or impractical	Package Insert	See Package Insert for new information on biologics	P	Johnson/Johnson Wound Management	NA	
155.	12/27/2007	AndroGel	testosterone	Use in adolescent	Labeling	• Safety and efficacy in males < 18 years old have not been established	B	Unimed	8/22/2007	

	Labeling Date♦	Trade Name	Generic or Proper (Biologics●) Name	Indication(s) Studied	Product Labeling	Labeling Changes	BPCA (B)/ PREA (P)/ Rule (R)	Sponsor	PE Granted Date	N N P S
				boys with delayed puberty		• Improper use may result in acceleration of bone age and premature closure of epiphyses				
156.	12/27/2007	Voluven	6% Hydroxyethyl Starch 130/0.4 In 0.9% Sodium Chloride Injection●	Plasma volume substitute for treatment and prophylaxis of hypovolemia	Package Insert	See Package Insert for new information on biologics	P	Fresenius Kabi Norge AS	NA	
157.	12/19/2007	Hepsera	adefovir dipivoxil	Chronic hepatitis B virus infection	Labeling	• Extended indication from adults to pediatric patients 12 years and older • Not recommended for children <12 years of age. Efficacy was not significantly different from placebo in a clinical study in children <12 years • Safety ≥12 – < 18 years was similar to that observed in adults • Information on PK, AEs, clinical study, clinical resistance	B, P	Gilead	NA	
158.	12/12/2007	Derma-Smoothe /FS Topical Oil	fluocinolone	Treatment of atopic dermatitis in pediatric patients 3 months and older for up to 4 weeks		• Extended age range down to 3 months • Effectiveness and safety are not established in children less than 3 months old • Safety was evaluated in two pediatric clinical studies (including facial use) • Pediatric dosing and administration information provided • Studies waived in children under 3 months of age due to safety concerns of adrenal suppression • New indication	P	Hill	NA	
159.	11/29/2007	Diovan	valsartan	Hypertension	Labeling	• Labeling for 6-16 years of age • Not recommended for pediatric patients less than 6 years due to safety findings possibly related to treatment or with glomerular filtration rate < 30mL/min/1.73m2 • Information on dose, clinical studies in 1-16 years and pharmacokinetics • No relevant differences were identified between adverse experience profile for pediatric patients and that previously reported for adult patients • Information on preparation of a suspension	B	Novartis	8/8/2007	
160.	11/29/2007	Triesence 40mg/mL	triamcinolone acetonide injectable suspension	Visualization during vitrectomy	Labeling	• Efficacy and safety of corticosteroids in the pediatric population are based on the well-established course of effect of corticosteroids, which is similar in pediatric and adult populations • Adverse effects of corticosteroids in pediatric patients are similar to those in adults • New indication	P	Alcon Research, Ltd.	NA	✓

	Labeling Date♦	Trade Name	Generic or Proper (Biologics●) Name	Indication(s) Studied	Product Labeling	Labeling Changes	BPCA (B)/ PREA (P)/ Rule (R)	Sponsor	PE Granted Date	NNPS
161.	11/21/2007	Omnaris Nasal Spray	ciclesonide	Treatment of seasonal allergic rhinitis (SAR) in patients 6 through less than 12 years of age	Labeling	• Indication extended down to 6 years of age • Pediatric dosing information provided • Two clinical studies evaluated safety in children 6 to 11 years of age and the overall incidence of adverse events was comparable to those treated with placebo • Efficacy in children 2 to 5 years of age was not established in clinical trials conducted in this age group. • Waiver of studies in children ages 0 to less than 2 years of age for SAR because of local and systemic safety concerns as well as lack of disease and/or diagnosis difficulties in children • New indication	P	Nycomed US Inc.	NA	
162.	11/9/2007	Kaletra Oral Solution, 80 mg/20 mg & Kaletra (lopinavir /ritonavir) Tablets, 200 mg/50 mg	lopinavir/ ritonavir	HIV -1 protease inibitor indicated in combination with other antiretroviral agents for the treatment of HIV -1 infection.	Labeling	• Dosing and administration information provided for children • Use of a lower strength tablet in a twice daily dosing regimen for pediatric patients weighing greater than 15 kg • New dosing regimen	P	Abbott Laboratories	NA	✓
163.	10/30/2007	Combigan 0.2%/0.5 % ophthalmic solution	brimonidine tartrate/timolol maleate	Reduction of elevated intraocular pressure in patients with glaucoma or ocular hypertension	Labeling	• Safety and effectiveness supported by evidence from clinical studies in adults with additional data from a study in children with glaucoma ages 2 – 7 years old • Not recommended for use in children under the age of 2 years due to safety concerns based on reports of apnea, bradycardia, hypotension, hypothermia, hypotonia, and somnolence in infants • Safety and effectiveness have not been studied in children below the age of two years • New active ingredient	P	Allergan	NA	✓
164.	10/29/2007	Abilify	aripiprazole	schizophrenia	Labeling	• Extended schizophrenia indication from adults to adolescents 13–17 years • Safety and effectiveness in pediatric patients with bipolar mania or agitation associated with schizophrenia or bipolar mania have not been established • Efficacy for the maintenance treatment of schizophrenia in the pediatric population has not been evaluated • In 6-week placebo controlled efficacy trial in patients 13 – 17 years with Schizophrenia 30 mg/day was not shown to be more efficacious than 10 mg/day • Common adverse events observed were extrapyramidal disorder, somnolence, and tremor; these 3 AEs appear to have a possible dose	B	Otsuka	11/14/2007	

	Labeling Date♦	Trade Name	Generic or Proper (Biologics●) Name	Indication(s) Studied	Product Labeling	Labeling Changes	BPCA (B)/ PREA (P)/ Rule (R)	Sponsor	PE Granted Date	N N P S
						response relationship • Information on dose, AEs, clinical studies				
165.	9/28/2007	Lamisil Oral Granules	terbinafine	Tinea capitis	Labeling	• New indication in 4 years and older • Two randomized safety and efficacy trials were conducted in patients 4 to 12 years old with tinea capitis. Terbinafine was dosed on a mg/kg basis and treated for 6 weeks • Although no hepatotoxicity was seen during trials, pre-treatment serum transaminases tests are advised. • The most common adverse events observed in the trials were nasopharyngitis, headache, pyrexia, cough, vomiting, and upper respiratory tract infection • New 125 mg and 187.5 mg oral granule formulations developed; take with food • Information on dose, PK parameters, AE profile, and instructions for use	B	Novartis	12/4/2006	
166.	9/20/2007	Norditropin Cartridges	somatropin (rDNA origin)	Treatment of short stature in children with Turner syndrome	Labeling	• Safety and effectiveness based on studies in pediatric patients • New Warning: Patients with Turner syndrome should be evaluated carefully for otitis media and other ear disorders since these patients have an increased risk of ear and hearing disorders. Somatropin treatment may increase the occurrence of otitis media in patients with Turner syndrome. In addition, patients with Turner syndrome should be monitored closely for cardiovascular disorders (e.g., stroke, aortic aneurysm/dissection, hypertension) as these patients are also at risk for these conditions • Information on recommended dosing, adverse events (AEs) and clinical studies • New indication	P	Novo Nordisk	NA	
167.	9/11/2007	Levaquin	levofloxacin	Community-acquired pneumonia	Labeling	• Levofloxacin is not indicated for pediatric patients < 18 years of age • In a prospective, long-term, surveillance study, levofloxacin treated children had a significantly higher incidence of musculoskeletal (MS) disorders (arthralgia, arthritis, tendonopathy, and gait abnormality) compared to non-fluoroquinolone-treated children • Information on clinical studies, AE profile	B, P	Ortho-McNeil	3/14/2007	
168.	8/22/2007	Risperdal	risperidone	Schizophrenia; short-term treatment of acute manic or mixed Episodes associated with Bipolar I Disorder	Labeling	• Extended schizophrenia indication from adults to adolescents 13–17 years; extended bipolar mania indication from adults to children and adolescents 10-17 years • Safety and effectiveness in children < 13 years of age with schizophrenia have not been established; safety and effectiveness in children < 10 years of age with bipolar mania have not been established • No additional benefit was seen above 3 mg/day in schizophrenia studies and 2.5 mg/day in the Bipolar mania study; higher doses were	B	Johnson & Johnson	2/28/2007	

	Labeling Date♦	Trade Name	Generic or Proper (Biologics●) Name	Indication(s) Studied	Product Labeling	Labeling Changes	BPCA (B)/ PREA (P)/ Rule (R)	Sponsor	PE Granted Date	N N P S
						associated with more adverse events. Doses higher than 6 mg/day have not been studied. • Information on dose, clinical studies, AE profile				
169.	8/17/2007	Provigil	modafinil	Narcolepsy	Labeling	• Modafinil is not approved for use in pediatric patients for any indication • Safety and effectiveness were not demonstrated in a controlled 6-week study in 165 pediatric patients 5-17 years with narcolepsy • Serious rash, including Stevens-Johnson Syndrome, requiring hospitalization and discontinuation of treatment has been reported in adults and children in association with the use of modafinil • In the controlled and open-label clinical studies, treatment emergent adverse events of the psychiatric and nervous system included Tourettes' syndrome, insomnia, hostility, increased cataplexy, increased hypnagogic hallucinations and suicidal ideation • Information on safety, AEs and clinical study	B	Cephalon, Inc	3/21/2006	
170.	8/16/2007	Zingo	lidocaine	Topical local analgesia prior to venipuncture or peripheral intravenous cannulation in children 3-18 years of age	Labeling	• Summary pending	P	Anesiva	NA	
171.	7/18/2007	Toprol XL	metoprolol	Hypertension	Labeling	• A study in 144 pediatric hypertensive pediatric patients aged 6 - 16 years did not meet its primary endpoint. However, some study endpoints demonstrated effectiveness • Adverse event profile similar to adults • Safety and effectiveness have not been established in patients < 6 years of age • Information on PK parameters, clinical studies, and dose	B	AstraZeneca	7/27/2006	
172.	6/14/2007	Lexiva Oral Suspension	fosamprenavir	Treatment of HIV infection in patients 2-18 years of age	Labeling	• Effectiveness and safety were established in two clinical studies of pediatric patients 2-18 years of age • Adverse event profile is similar to that of adults with the exception of vomiting, which, regardless of causality, occurred more frequently among pediatric patients • Dosing information provided • Studies waived in children 0-1 month of age and deferred in children 1 month - 2 years of age • New dosage form	P	GlaxoSmith Kline	NA	
173.	6/12/2007	Extina Foam,	ketoconazole	Topical treatment of	Labeling	• Effectiveness and safety were established in a clinical study that	P	Stiefel Laboratorie	NA	

	Labeling Date♦	Trade Name	Generic or Proper (Biologics●) Name	Indication(s) Studied	Product Labeling	Labeling Changes	BPCA (B)/ PREA (P)/ Rule (R)	Sponsor	PE Granted Date	N N P S
		2%		seborrheic dermatitis in immunocompetent patients 12 years of age and older		included 44 patients from 12-17 years of age • Studies waived in children 0-12 years of age • New dosage form		s		
174.	6/8/2007	Betoptic S	betaxolol	Elevated intraocular pressure in patients with chronic open-angle glaucoma or ocular hypertension	Labeling	• Extended indication from adults to pediatric patients • The adverse reaction profile was comparable to that seen in adults	B	Alcon	2/28/2007	
175.	6/8/2007	Timolol GFS	timolol	Elevated intraocular pressure in patients with chronic open-angle glaucoma or ocular hypertension	Labeling	• Extended indication from adults to pediatric patients • The adverse reaction profile was comparable to that seen in adults	B	Falcon Pharmaceuticals	2/28/2007	
176.	5/30/2007	Zyflo CR Extended Release Tablets	zileuton	Prevention and chronic treatment of asthma in children 12 years of age and older	Labeling	• Should not be used in children under 12 years of age • Effectiveness was established in clinical studies that included pediatric patients 12 years of age and older • Short-term and long-term safety were established in clinical studies that included pediatric patients 12 years of age and older • Studies waived in children 0-4 years of age and deferred in children 5-11 years of age • New dosage form	P	Critical Therapeutics	NA	
177.	5/25/2007	Xyzal Tablets 5 mg	levocetirizine	Relief of symptoms associated with seasonal allergic rhinitis and perennial allergic rhinitis in adults and children 6 years of age or older, and for the treatment of the uncomplicated skin manifestations	Labeling	• Summary pending	P	UCB	NA	

	Labeling Date♦	Trade Name	Generic or Proper (Biologics●) Name	Indication(s) Studied	Product Labeling	Labeling Changes	BPCA (B)/ PREA (P)/ Rule (R)	Sponsor	PE Granted Date	NNPS
				of chronic idiopathic urticaria in adults and children 6 years of age or older						
178.	5/18/2007	Locoid Lotion 0.1%	hydrocortisone butyrate	Treatment of mild to moderate atopic dermatitis in children 3 months of age and older	Labeling	• Effectiveness established in one study of 284 patients from 3 months to 18 years of age • Information provided on HPA axis suppression from one safety study with Locoid Lotion of 84 pediatric patients from 3 months to 18 years of age with moderate to severe atopic dermatitis affecting at least 25% of body surface area • Studies waived in children < 3 months of age • New dosage form	P	Ferndale Labs	NA	
179.	4/27/2007	Azasite Ophthalmic Solution 1%	azithromycin	Treatment of bacterial conjunctivitis caused by certain microorganisms in patients down to 1 year of age	Labeling	• Effectiveness and safety were established in controlled clinical trials including patients down to 1 years of age • Dosing information provided • New dosage form	P	InSite Vision	NA	
180.	4/19/2007	Valtropin	somatropin (rDNA origin)	Short stature in children with Turner Syndrome	Labeling	• Summary pending	P	LG Life	NA	
181.	4/12/2007	Altabax Ointment 1%	retapamulin	Treatment of impetigo in patients 9 months of age and older	Labeling	• Safety and effectiveness established in studies that included 588 pediatric patients from 9 months of age to 17 years of age • Studies waived in children 0-2 months of age and deferred in children 2-9 months of age • New active ingredient	P	GlaxoSmith Kline	NA	
182.	3/28/2007	Ambien	zolpidem	Insomnia associated with ADHD	Labeling	• Safety and effectiveness have not been established in pediatric patients with insomnia associated with ADHD • In an 8-week controlled study in 201 pediatric patients 6-17 years, psychiatric and nervous system disorders comprised > 5% of treatment emergent adverse events, including dizziness (23.5%) headache (12.5%) and hallucinations (7.4%); treatment was discontinued due to an adverse event in 7.4%	B	Sanofi Aventis	11/20/2006	
183.	3/22/2007	Aldara	imiquimod	Molluscum contagiosum	Labeling	• Efficacy in patients 2 – 12 years for the treatment of molluscum contagiosum was not demonstrated in two clinical trials in 702 patients • Information on clinical studies and AEs	B	Graceway Pharmaceuticals	12/13/2006	

	Labeling Date♦	Trade Name	Generic or Proper (Biologics●) Name	Indication(s) Studied	Product Labeling	Labeling Changes	BPCA (B)/ PREA (P)/ Rule (R)	Sponsor	PE Granted Date	NNPS
184.	3/19/2007	Keppra Tablets Keppra Oral Solution	levetiracetam*	Adjunctive therapy in the treatment of primary generalized tonic-clonic seizures in children 6 years of age and older with idiopathic generalized epilepsy	Labeling	• Safety and effectiveness established in study that included patients down to 4 years of age • Pediatric dosing information added • Studies waived in children 1 month to 2 years of age and deferred in children 2-6 years of age • New indication	P	UCB	NA	
185.	2/23/2007	Coreg	carvedilol	Heart failure	Labeling	• Effectiveness has not been established in patients < 18 years • In a double-blind trial of 161 children, 2 months to 17 years with chronic heart failure receiving standard background treatment, randomized to placebo or carvedilol, carvedilol demonstrated reduction of heart rate 4-6 beats per minute • There was no significant effect of treatment on clinical outcomes after 8 months of follow-up • AEs occurring in ≥ 10% of patients treated with carvedilol included chest pain (17%), dizziness (13%), and dyspnea (11%)	B, P	GlaxoSmith Kline	11/8/2006	
186.	2/23/2007	Vyvanse Capsules	lisdexamfetamine	Treatment of ADHD in children 6 to 12 years of age	Labeling	• Effectiveness established in two studies of patients 6-12 years of age • Long-term effectiveness of more than 4 weeks has not been established • Studies waived in children 0-5 years of age and deferred in children 13-17 years of age • New active ingredient	P	New River	NA	
187.	2/7/2007	Actiq	fentanyl	Treatment of breakthrough pain in opioid tolerant children	Labeling	• Safety and efficacy in patients below the age of 16 years was not established in a clinical trial of 15 patients 5 to 15 years • Information on PK parameters and clinical studies	B, P	Cephalon	NA	
188.	1/10/2007	Eloxatin	oxaliplatin	Solid tumors	Labeling	• The effectiveness of oxaliplatin in children has not been established • No significant activity observed in 2 Phase I and 2 Phase II trials in 159 patients ages 7 months to 22 years with solid tumors • Information on clinical studies and AEs	B	Sanofi-Aventis	9/27/2006	
189.	12/22/2006	Emtriva	emtricitabine	HIV-1 infection in combination with other antiretroviral agents	Labeling	• Efficacy in preventing or treating HIV in neonates to 3 month olds could not be determined after a PK study in 20 neonates born to HIV positive mothers • Information on dose in 0-3 months, additional safety and PK parameters	B	Gilead Sciences	5/24/2006	

	Labeling Date♦	Trade Name	Generic or Proper (Biologics●) Name	Indication(s) Studied	Product Labeling	Labeling Changes	BPCA (B)/ PREA (P)/ Rule (R)	Sponsor	PE Granted Date	N N P S
190.	12/20/2006	Colazal	balsalazide	Mildly to moderately active ulcerative colitis in patients 5 years of age and older	Labeling	• Extended indication from adults to patients 5 years and older • Dosing can be initiated at either 6.75 or 2.25 g/day • PK of balsalazide, and metabolites showed very large inter-patient variability similar to that seen in adults • AEs were similar to those seen in adults	B, P	Salix	8/23/2006	
191.	12/15/2006	Celebrex	celecoxib	Relief of the signs and symptoms of juvenile rheumatoid arthritis (JRA)	Labeling	• New indication in 2 years and older • Has not been studied in patients < 2 years, in patients with body weight < 10 kg, or in patients with active systemic features • Celecoxib should be used only with caution in patients with systemic onset JRA due to the risk for serious adverse reactions including the risk of disseminated intravascular coagulation • The long-term cardiovascular toxicity in children has not been evaluated; it is unknown if the long-term risk may be similar to that seen in adults • New 50 mg capsule developed • Information on adding contents of a capsule to applesauce. for patients with difficulty swallowing capsules • Information on dose, clinical studies, PK parameters, AEs	B	Pfizer	8/23/2006	
192.	12/15/2006	Suprane	desflurane	Safety study of 2 agents used for maintenance of anesthesia in non-intubated patients	Labeling	• Not indicated for maintenance of anesthesia in non-intubated pediatric patients • In a clinical safety trial in patients 2 - 16 years, desflurane and isoflurane were compared for maintenance of anesthesia in non-intubated patients to assess the incidence of respiratory adverse events. Desflurane was associated with higher rates of coughing, laryngospasm and secretions with an overall rate of respiratory events of 39%. 5% of pediatric patients 2-16 years old exposed to desflurane, experienced severe laryngospasm • The incidence of respiratory events was highest in children aged 2-6 years; therefore, similar studies in children under the age of 2 years were not initiated. • Additional information on clinical studies and AEs	B	Baxter	9/13/2006	
193.	11/7/2006	Ziana Gel	clindamycin; tretinoin	Treatment of acne vulgaris in patients 12 years of age and older	Labeling	• Effectiveness and safety based on two studies in patients 12 years of age and older • New active ingredient	P	Dow	NA	
194.	11/1/2006	Humatrope for injection	somatropin (rDNA origin)	Treatment of short stature or growth failure in children with short stature	Labeling	• Effectiveness established from one 2-year study for SHOX in 52 pediatric patients • Information on adverse events provided • Dosing information provided	P	Lilly	NA	

	Labeling Date♦	Trade Name	Generic or Proper (Biologics●) Name	Indication(s) Studied	Product Labeling	Labeling Changes	BPCA (B)/ PREA (P)/ Rule (R)	Sponsor	PE Granted Date	N N P S
				homeobox-containing gene (SHOX) deficiency		• New indication				
195.	10/20/2006	Desonate Gel	desonide	Treatment of mild to moderate atopic dermatitis in children 3 months of age and older	Labeling	• Effectiveness established from two studies in patients 3 months to 18 years of age • Not recommended for use in patients under 3 months of age • Treatment should not exceed 4 consecutive weeks • HPA axis suppression studied in patients 6 months of age to 6 years of age • New dosage form	P	Dow	NA	
196.	10/19/2006	Zaditor ophthalmic solution#	ketotifen	Temporary relief of itchy eyes in children 3 years of age and older OTC	Labeling	• No new studies submitted • New indication	P	Novartis	NA	✓
197.	10/16/2006	Allegra	fexofenadine	Seasonal allergic rhinitis (SAR) uncomplicated skin manifestations of chronic idiopathic urticaria (CIU)	Labeling	• New suspension developed • Suspension indicated for the treatment of SAR in 2 – 11 years based on the PK comparisons in adult and pediatric patients and an extrapolation of efficacy in adults; Suspension indicated for the treatment of CIU in 6 months – 11 years based on the PK comparisons in adults and children and an extrapolation of efficacy in adults • Safety and effectiveness of suspension in pediatric patients under 6 months of age have not been established • Additional information on dose, PK parameters, safety and AEs	B	Aventis	1/27/2003	
198.	10/13/2006	Tirosint capsules #	levothyroxine	Replacement or supplemental therapy in hypothyroidism; treatment or prevention of euthyroid goiters	Labeling	• Contraindicated in infants, small children, or any child who may be unable to swallow a capsule. • Dosing information provided • Information to monitor disease provided • No clinical studies submitted • New dosage form	P	Institute Biochimique SA	NA	
199.	10/6/2006	Risperdal Tablets Risperdal Oral Solution Risperdal M-Tabs	risperidone*	Treatment of irritability associated with autistic disorder in children 5 years of age and older	Labeling	• Effectiveness and safety established based on two 8 week studies in patients 5-16 years of age and one long-term study of 4-6 months • Studies waived in children under 2 years of age due to difficulty to diagnose and treat this population • New indication	P	Janssen	NA	

	Labeling Date♦	Trade Name	Generic or Proper (Biologics●) Name	Indication(s) Studied	Product Labeling	Labeling Changes	BPCA (B)/ PREA (P)/ Rule (R)	Sponsor	PE Granted Date	N N P S
200.	10/5/2006	UV Protective Suncare # Capital Soleil 20# Anthelios 20# UV Expert 20#	avobenzone; ecamsule; octocrylene; titanium	Prevention of sunburn and protection from UVA and UVB rays in children 6 months of age and older OTC	Labeling	• No clinical studies submitted to support • Age range based on monograph • Studies deferred in children under 6 months of age • New active ingredient	P	L'Oreal	NA	
201.	9/29/2006	DuraPrep Surgical Solution#	iodine; isopropyl alcohol	Preoperative skin preparation for use in children 2 months of age and older OTC	Labeling	• Effectiveness based on determination that permeability of skin in children > 2 months of age is essentially that of adult skin • Studies waived in children under 2 months of age for safety reasons and includes the following statement in the label: Do not use in children under 2 months of age due to excessive skin irritation and transient hypothyroidism. • New active ingredient	P	3M Health	NA	
202.	9/29/2006	Fuzeon	enfuvirtide	HIV-1 infection in treatment-experienced patients with evidence of HIV-1 replication despite ongoing antiretroviral therapy	Labeling	• Additional safety and efficacy data and AE information from clinical study in 5-16 year olds • Insufficient data to provide dosing recommendations in patients < 6 years	B, P	Hoffmann-La Roche	NA	
203.	9/28/2006	Azopt ophthalmic suspension	brinzolamide	Elevated intraocular pressure	Labeling	• IOP-lowering efficacy was not demonstrated in a 3-month controlled clinical study in which brinzolamide was dosed only twice a day in pediatric patients 4 weeks to 5 years of age	B	Alcon	6/28/2006	
204.	9/28/2006	Betaxon ophthalmic suspension	levobetaxolol	Elevated intraocular pressure	Labeling	• Extended indication from adults to pediatric patients • The adverse event profile was comparable to that seen in adults and elderly patients	B, P	Alcon	6/28/2006	

	Labeling Date♦	Trade Name	Generic or Proper (Biologics●) Name	Indication(s) Studied	Product Labeling	Labeling Changes	BPCA (B)/ PREA (P)/ Rule (R)	Sponsor	PE Granted Date	N N P S
205.	9/27/2006	Gleevec	imatinib mesylate	Treatment of newly diagnosed pediatric patients with Philadelphia chromosome positive (Ph+) chronic myeloid leukemia (CML) in chronic phase	Labeling	• Extended age range for the treatment of newly diagnosed CML down to pediatric patients • There are no data in children < 2 years of age • Follow-up in children with newly diagnosed Ph+ chronic phase CML is limited • Information on hematologic toxicities, AE profile, clinical studies and dosing guidelines new for newly diagnosed pediatric patients	B, P	Novartis	6/9/2006	
206.	9/22/2006	Lamictal Tablets Lamictal Chewable Dispersible Tablets	lamotrigine*	Adjunctive therapy for primary generalized tonic-clonic seizures in children 2 years of age and older	Labeling	• Effectiveness established in study with patients down to 2 years of age • Revised boxed warning to remove restrictions on use in pediatric patients • New indication	P	GlaxoSmith Kline	NA	
207.	9/19/2006	Verdeso Foam	desonide	Treatment of mild to moderate atopic dermatitis in patients 3 months of age and older	Labeling	• Effectiveness established from studies in 581 pediatric patients 3 months to 17 years of age • Effect on HPA axis function was investigated in pediatric patients 6 months to 17 years of age in one study of 75 patients • Safety has not been evaluated in patients below 3 months of age • Use for the minimum amount of time necessary due to the potential to suppress HPA axis treatment should not exceed 4 consecutive weeks • New dosage form	P	Connetics	NA	
208.	9/15/2006	Noxafil Oral Suspension	posaconazole	Prevention of invasive Aspergillis and Candida infections in patients 13 years of age and older	Labeling	• Information on PK and safety studies in patients 13-17 years of age • Safety profile in patients 8-17 years of age similar to adults • Safety and effectiveness in patients below 13 years of age have not been established • Additional information on pharmacokinetics provided in patients down to 8 years of age • Studies deferred in children 0-12 years of age • New drug	P	Schering	NA	
209.	7/28/2006	Xolegel Gel	ketoconazole	Treatment of seborrheic dermatitis in children 12 years of age	Labeling	• Effectiveness established from studies in patients 12 years of age and older • Safety and effectiveness in pediatric patients below 12 years of age have not been establishedstudies waived in children 0-12 years of age	P	Barrier Therapeutics	NA	

	Labeling Date♦	Trade Name	Generic or Proper (Biologics●) Name	Indication(s) Studied	Product Labeling	Labeling Changes	BPCA (B)/ PREA (P)/ Rule (R)	Sponsor	PE Granted Date	NNPS
				and older		• New dosage form				
210.	7/27/2006	Sodium Chloride Injection #	sodium chloride	Use in flushing compatible contrast agents through IV administration sets into indwelling intravascular access devices	Labeling	• Safety of manual injection in pediatric patients is supported by reported clinical experience with IV infusion and flush safety and effectiveness of Sodium Chloride Injection, USP 0.9% administered by power injection in pediatric patients have not been established • Administration to pediatric patients by power injection is not recommended • To minimize the risk of fluid overload, the smallest dose necessary for manually flushing contrast agent through the vascular access line should be used • Manual injection to pediatric patients should take into account the patient's weight, fluid status, and concomitant medical conditions to determine if use is appropriate • New indication	P	Tyco Healthcare	NA	
211.	7/21/2006	Anthelios SX Cream	avobenzone; ecamsule; octocrylene	Prevention of sunburn and protection from UVA and UVB rays in children 6 months of age and older OTC	Labeling	• Effectiveness extrapolated from adult studies • Safety studies included pediatric patients 6 months of age and older • Age range based on monograph • Deferred studies in children < 6 months of age • New active ingredient	P	L'Oreal USA	NA	
212.	7/21/2006	Symbicort Inhalation Aerosol	Formoterol / budesonide*	Long-term maintenance treatment of asthma in children 12 years of age and older	Labeling	• Effectiveness and safety in patients 12 years of age and older established in studies up to 12 months long • PK studies in patients 6-11 years of age • Effectiveness in patients 6 to < 12 years of age has not been established • Overall safety profile in patients 6 to < 12 years of age was similar to that observed in patients 12 years of age and older • Studies waived in children 0-6 years of age; deferred in children 6-12 years of age • New active ingredient	P	AstraZeneca	NA	
213.	6/29/2006	Lidocaine and Tetracaine Cream	lidocaine; tetracaine	Topical local analgesia for superficial dermatological procedures	Labeling	• Studies failed to show effectiveness over placebo in reducing the pain associated with venipuncture in pediatric patients 5-17 years of age • New active ingredient	P	ZARS	NA	
214.	5/10/2006	Sandostatin LAR	octreotide	Weight loss due to hypothalamic obesity from	Labeling	• A randomized double-blind, placebo-controlled study in 60 patients aged 6 –17 years with hypothalamic obesity from cranial insult did not demonstrate efficacy and safety of octreotide as a weight loss agent; Mean BMI increased 0.1 kg/m2 in drug treated patients compared to 0.0	B	Novartis	1/12/2006	

	Labeling Date♦	Trade Name	Generic or Proper (Biologics●) Name	Indication(s) Studied	Product Labeling	Labeling Changes	BPCA (B)/ PREA (P)/ Rule (R)	Sponsor	PE Granted Date	N N P S
				cranial insult		kg/m2 in control-treated patients • No unexpected AEs were observed; However, the incidence of new cholelithiasis in this pediatric population (33%) was higher than that seen in adult indications • Information on PK parameters and AEs				
215.	5/8/2006	Solodyn Extended -Release Tablets	minocycline	Treatment of inflammatory lesions of non-nodular moderate to severe acne vulgaris in children 12 years of age and older	Labeling	• Only used to treat inflammatory lesions of non-nodular moderate to severe acne vulgaris • Safety and effectiveness established from studies in patients 12 years of age and older • Safety and effectiveness in pediatric patients below 12 years of age has not been established • Studies waived in children 0-11 years of age • New dosage form	P	Medicis	NA	
216.	4/28/2006	Nexium	esomeprazole	Short-term treatment of GERD	Labeling	• Use in adolescent patients 12 to 17 years of age is supported by extrapolation from studies in adults, and safety and PK studies performed in adolescent patients • Safety and effectiveness in patients < 12 years has not been established • Safety and effectiveness for other pediatric uses have not been established • Information on dose, treatment related AEs, clinical study	B	AstraZeneca	5/1/2009	
217.	4/27/2006	Genotropin Injection	somatropin (rDNA origin)	Long-term treatment of growth failure associated with Turner syndrome	Labeling	• Indicated for use in pediatric patients with open epiphyses • Effectiveness and safety based on studies in pediatric patients • New indication	P	Pharmacia & Upjohn	NA	
218.	4/10/2006	Lescol and Lescol XL	fluvastatin	Heterozygous familial hypercholesterolemia as an adjunct to diet	Labeling	• New indication in adolescent boys and girls (at least one year post-menarche) 10-16 years of age, with heterozygous familial hypercholesterolemia • Information on dose, AE profile and clinical studies	B, P	Novartis	12/15/2005	
219.	4/6/2006	Daytrana	methylphenidate	ADHD	Labeling	• Summary pending	P	Shire	NA	
220.	3/29/2006	Relenza	zanamivir	Prevention of influenza in children 5 years of age and older	Labeling	• Safety and effectiveness for prophylaxis based on 4 clinical studies in patients 5-16 years of age • No differences in safety and effectiveness were observed between pediatric and adult subjects. • Dosing information provided • Studies waived in children <5 years of age	P	GlaxoSmith Kline	NA	

	Labeling Date♦	Trade Name	Generic or Proper (Biologics●) Name	Indication(s) Studied	Product Labeling	Labeling Changes	BPCA (B)/ PREA (P)/ Rule (R)	Sponsor	PE Granted Date	N N P S
						• New indication				
221.	3/16/2006	Avapro	irbesartan	Hypertension	Labeling	• In a study at a dose up to 4.5 mg/kg once daily, irbesartan did not appear to lower blood pressure effectively in pediatric patients ages 6 to 16 years	B	Sanofi-Synthelabo	9/16/2004	
222.	3/2/2006	Vanos Cream	fluocinonide	Relief of the inflammatory and pruritic manifestations of corticosteroid responsive dermatoses in children 12 years of age and older	Labeling	• Use in pediatric patients younger than 12 years of age is not recommended • Effectiveness extrapolated from adult studies • Safety in patients 12 to 17 years of age was similar to that observed in adults • Information provided on HPA axis suppression from safety studies with Vanos Cream in 4 cohorts of pediatric patients (3 months - 18 years of age) with atopic dermatitis • Studies waived in children 0-11 years of age • New indication	P	Medicis	NA	
223.	2/28/2006	Flovent HFA	fluticasone propionate	Asthma in 4 - 11 years	Labeling	• Flovent HFA should be administered by the orally inhaled route only in patients 4 years and older. • Clinical studies were conducted in children with asthma 6 months to less than 4 years • Information added to Pediatric Use	P	GlaxoSmith Kline	NA	
224.	2/16/2006	Vusion Ointment	miconazole	Adjunctive treatment of diaper dermatitis in children 4 weeks of age and older	Labeling	• Indicated for use in immunocompetent children • Presence of candidal infection should be established by microscopic evaluation prior to initiating treatment • Effectiveness based on three clinical studies in infants and toddlers • Safety when used for more than 7 days is not known • New active ingredient	P	Barrier Therapeutics	NA	
225.	2/3/2006	ProAir HFA Inhalation Aerosol	albuterol	Prevention of exercise-induced bronchospasm in children 12 years of age and older	Labeling	• Expands use from previously approved bronchospasm with reversible obstructive airway disease • Effectiveness based on study in adults and adolescents • Safety and effectiveness in pediatric patients below 12 years of age have not been established • New indication	P	IVAX	NA	
226.	2/1/2006	Clarinex-D 12 Hour Extended Release	desloratadine*/ pseudoephedrine	Relief of nasal and non-nasal symptoms of seasonal allergic rhinitis	Labeling	• Approval based on two safety and effectiveness studies in patients down to 12 years of age • Not an appropriate dosage form for use in pediatric patients below 12 years of age.	P	Schering	NA	

	Labeling Date♦	Trade Name	Generic or Proper (Biologics●) Name	Indication(s) Studied	Product Labeling	Labeling Changes	BPCA (B)/ PREA (P)/ Rule (R)	Sponsor	PE Granted Date	N N P S
		Tablets		in children 12 years of age and older		• Studies waived in children < 12 years of age • New dosing regimen				
227.	12/21/2005	Fosamax	alendronate	Severe osteogenesis imperfecta	Labeling	• Alendronate is not indicated for use in children • The efficacy and safety were examined in a randomized, double-blind, placebo-controlled two-year study of 139 patients, 4-18 years old, with severe osteogenesis imperfecta • Treatment with alendronate did not reduce the risk of fracture • There were no statistically significant differences between the alendronate and placebo groups in reduction of bone pain • Information on PK parameters, AE profile, and clinical studies	B	Merck	4/28/2003	
228.	12/21/2005	TamiFlu	oseltamivir	Prophylaxis in pediatric patients 1 year to <13 years of age	Labeling	• Information on postmarketing clinical study in patients 1 to 12 years	P	Roche	NA	
229.	12/8/2005	Meridia	sibutramine	Obesity	Labeling	• The data are inadequate to recommend the use of sibutramine for the treatment of obesity in pediatric patients • Efficacy in obese adolescents has not been adequately studied • Sibutramine's mechanism of action inhibiting the reuptake of serotonin and norepinephrine is similar to that of some antidepressants • It is unknown if sibutramine increases the risk of suicidal behavior or thinking in pediatric patients • In a study of adolescents with obesity in which 368 patients were treated with sibutramine and 130 patients with placebo, one patient in each group attempted suicide. Suicidal ideation was reported by 2 sibutramine-treated patients and none of the placebo patients	B	Abbott	10/6/2004	
230.	12/1/2005	Effexor XR Extended -Release Capsules	venlafaxine	Social anxiety disorder	Labeling	• Provided additional safety data for changes in weight, height, and appetite occurring in pediatric patient • Information based on a clinical study of patients with SAD • New indication (not approved in pediatric patients)	P	Wyeth	NA	
231.	11/28/2005	Amaryl	glimepiride	Type-2 Diabetes Mellitus	Labeling	• Data are insufficient to recommend pediatric use of glimepiride • In an active-controlled, single-blind, 24-week trial, 272 pediatric patients aged 8 to 17 years with Type 2 diabetes were randomized to treatment with glimepiride or metformin. Trial suggested differences favoring metformin • AE profile in the pediatric population was similar to that for adults • Information on PK parameters	B, P	Aventis	6/9/2005	

	Labeling Date♦	Trade Name	Generic or Proper (Biologics●) Name	Indication(s) Studied	Product Labeling	Labeling Changes	BPCA (B)/ PREA (P)/ Rule (R)	Sponsor	PE Granted Date	N N P S
232.	11/9/2005	Fluocinolone Acetonide Oil	fluocinolone	Chronic eczematous external otitis (outer ear) in children 2 years of age and older	Labeling	• Effectiveness established in studies of patients 2 years of age and older • New indication	P	Hill Dermaceuticals	NA	
233.	10/28/2005	Trileptal	oxcarbazepine	Use as adjunctive therapy in children aged 2 years and above with epilepsy	Labeling	• Extended adjunctive therapy age range from 4 years down to 2 years • No evidence drug was effective as adjunctive therapy in patients < 2 years • In clinical studies as adjunctive therapy, apparent clearance (L/hr/kg) decreased when age increased such that children 2 to <4 years of age may require up to twice the dose per body weight compared to adults; and children 4 to ≤12 years of age may require a 50% higher dose per body weight compared to adults • Approximately 11% of pediatric patients < 4 years discontinued treatment because of adverse events including convulsions, status epilepticus and ataxia • Information on dose, PK parameters, AE profile and clinical studies	B	Novartis	3/2/2005	
234.	10/6/2005	Norvir	ritonavir	Treatment of HIV-infection in combination with other antiretroviral agents	Labeling	• Extended age range from 2 years down to 1 month • AE profile in the pediatric population was similar to that for adults • Information on dose and PK parameters	B	Abbott	6/14/2005	
235.	9/28/2005	Emtriva	emtricitabine	HIV-1 infection in combination with other antiretroviral agents	Labeling	• Safety and effectiveness in pediatric patients 3 months and older supported by data from 3 open-label, nonrandomized clinical studies • Safety and effectiveness in patients < 3 months have not been established • Relative bioavailability of Emtriva oral solution is approximately 80% of Emtriva capsules. Thus, maximum dosage is different for these 2 formulations: Solution max - 240 mg once daily; Capsules max - children weighing > 33 kg one 200 mg capsule once daily • The AE profile in pediatric patients was comparable to that observed in adults • Information on dose, PK parameters, AE profile and clinical studies •	B, P	Gilead Sciences	5/24/2006	
236.	9/13/2005	NovoLog	insulin aspart recombinant injection	Diabetes Mellitus	Labeling	• In clinical studies comparing NovoLog to regular human insulin in patients 2 to 18 years with type 1 diabetes, NovoLog achieved glycemic control comparable to regular human insulin • The incidence of hypoglycemia was similar for both treatment groups	B	Novo Nordisk	5/24/2005	
237.	8/11/2005	Mobic	meloxicam	Relief of signs and symptoms of	Labeling	• Safety and efficacy established in patients 2 years of age and older • Clinical studies evaluated doses ranging from 0.125 mg/kg/day to 0.375	B, P	Boehringer Ingelheim	4/15/2005	

	Labeling Date♦	Trade Name	Generic or Proper (Biologics●) Name	Indication(s) Studied	Product Labeling	Labeling Changes	BPCA (B)/ PREA (P)/ Rule (R)	Sponsor	PE Granted Date	N N P S
				pauciarticular or polyarticular course Juvenile Rheumatoid Arthritis		mg/kg/day. There was no additional benefit demonstrated by doses above 0.125 mg/kg/day in the clinical trials. The lowest effective dose should be used • Adverse events in children were similar to those in adults including skin reactions and gastrointestinal bleed risk • Information on dose, PK parameters, AE profile and clinical studies				
238.	8/4/2005	Loperamide Hydrochloride Soft Gelatin Capsules #	loperamide	Control symptoms of diarrhea in children 12 years of age and older	Labeling	• New dosage form; new dosing regimen • No new clinical studies • Bioequivalence study in adults compared the current OTC drug (Imodium caplet) and this drug • Studies waived in children 0-2 years of age	P	Banner Pharmacaps	NA	✓
239.	7/29/2005	Avandia	rosiglitazone	Type 2 Diabetes Mellitus	Labeling	• Data are insufficient to recommend pediatric use of rosiglitazone • In a 24 week double-blind controlled trial in children with type 2 diabetes mellitus, aged 10 to 17 years, with a baseline BMI of 33 kg/m2 were randomized to treatment with rosiglitazone or metformin • Mean change from baseline in HbA1c was -0.14% with rosiglitazone and -0.49% with metformin • There was an insufficient number of patients to establish statistically whether these observed mean treatment effects were similar or different • Weight gain similar to that in adults • Information on PK parameters, and AE profile	B	SB Pharmco	12/09/2004	
240.	7/27/2005	Singulair Oral Granules #, Tablets#, and Chewable Tablets#	montelukast	Relief of symptoms of perennial allergic rhinitis in children 6 months of age and older	Labeling	• Effectiveness was extrapolated from a allergic rhinitis study in patients 15 years of age and older • Safety in patients 6 to 23 months is supported by data from PK and safety and efficacy studies in asthma in this pediatric population and from adult PK studies • Studies waived in children < 6 months of age • New indication	P	Merck	NA	
241.	7/21/2005	Adderall XR	amphetamines mixed salts	ADHD	Labeling	• Expanded labeling for 13-17 year olds • On a mg/kg body weight basis children 6-12 years have a higher clearance than adolescents or adults. Body weight is the primary determinant • There was not adequate evidence that doses greater than 20 mg/day conferred additional benefit in a placebo-controlled study conducted in	B, P	Shire	10/28/2004	

	Labeling Date♦	Trade Name	Generic or Proper (Biologics●) Name	Indication(s) Studied	Product Labeling	Labeling Changes	BPCA (B)/ PREA (P)/ Rule (R)	Sponsor	PE Granted Date	N N P S
						adolescents aged 13-17 with ADHD • In a single-dose PK study in adolescents, isolated increases in systolic blood pressure (SBP) were observed in patients receiving 10 mg and 20 mg Adderall XR. Higher single doses were associated with a greater increase in SBP • Sustained increases in blood pressure should be treated with dose reduction and/or appropriate medication • Information on dose, PK parameters, and AE profile				
242.	6/29/2005	Topamax Tablets and Sprinkle Capsules	topiramate*	Initial monotherapy for partial onset or primary generalized tonic-clonic seizures in children 10 years of age and older	Labeling	• Effectiveness established in studies of patients down to 6 years of age • Use in patients who were converted to monotherapy from a previous regimen of other anticonvulsant drugs have not been established in controlled trials • Provides information regarding treatment-emergent decrease in serum bicarbonate and adverse events • Some patients in the study discontinued therapy due to adverse events; however, adverse events associated with discontinuing therapy included difficulty with concentration/attention • Studies waived in children 0-2 years of age; deferred in children 2-10 years of age • New indication	P	Johnson & Johnson	NA	
243.	6/21/2005	Keppra	levetiracetam	Adjunctive therapy in the treatment of partial onset seizures in patients with epilepsy	Labeling	• Extended indication from adults to patients 4 years and older • Safety and effectiveness have not been established in patients less than 4 years of age • PK analysis showed that clearance increased with an increase in body weight • Approximately 22% increase of apparent total body clearance of levetiracetam when co-administered with enzyme-inducing Anti-Epileptic Drugs (AEDs). Dose adjustment not necessary • 37.6% of pediatric patients reported behavioral symptoms compared to 13.3% in adults • Somnolence occurred in 22.8% in pediatric patients compared to 14.8% in adults • Information on dose, PK parameters, AE profile and clinical studies	B	UCB Pharma	6/3/2008	
244.	5/26/2005	Focalin XR Extended -Release Capsules	dexmethylphenidate	Treatment of Attention-Deficit Hyperactivity Disorder in children 6 years of age and older	Labeling	• Should not be used in children under 6 years of age • Effectiveness in patients age 6 years of age and older was established in clinical studies • PK studies also conducted • Long-term effects in children have not been established • New dosage form	P	Novartis	NA	
245.	5/25/2005	Merrem	meropenem	Treatment of	Labeling	• Supported by extrapolating safety and effectiveness from an adequate	P	AstraZenec	NA	

	Labeling Date♦	Trade Name	Generic or Proper (Biologics●) Name	Indication(s) Studied	Product Labeling	Labeling Changes	BPCA (B)/ PREA (P)/ Rule (R)	Sponsor	PE Granted Date	N N P S
		I.V.		complicated skin and skin structure infections in children 3 months of age and older		and well-controlled adult study and additional data from pediatric PK studies • Studies waived for children < 3 months of age • New indication		a		
246.	5/18/2005	Invanz	ertapenem	Complicated Intra-abdominal Infections; Complicated Skin and Skin Structure Infections; Community Acquired Pneumonia; Complicated Urinary Tract Infections; Acute Pelvic Infections	Labeling	• Approved for use down to 3 months of age. Efficacy extrapolated from studies in adults and supported by PK and safety studies in pediatric patients • Not recommended in infants under 3 months of age as no data are available • Not recommended in the treatment of meningitis in the pediatric population due to lack of sufficient CSF penetration • Information on dose, PK parameters, AE profile and clinical studies	B	Merck	2/11/2005	
247.	5/13/2005	Ortho Tri-Cyclen	norgestimate/ ethinyl estradiol	Evaluation of total hip bone mineral density in adolescent females with anorexia nervosa	Labeling	• No significant difference between Ortho Tri-Cyclen and placebo in mean change in total lumbar spine (L1-L4) and total hip bone mineral density in 123 adolescent females with anorexia nervosa in a double-blind, placebo-controlled, multicenter, one-year clinical trial	B	Ortho McNeil	12/18/2003	
248.	5/12/2005	Zyvox	linezolid	Central nervous system infections	Labeling	• PK data in pediatric patients with ventriculoperitoneal shunts showed variable cerebrospinal fluid (CSF) concentrations; therapeutic concentrations were not consistently achieved or maintained in the CSF • Use of linezolid for the empiric treatment of pediatric patients with central nervous system infections is not recommended • Additional information on efficacy in pediatric patients with infectious vancomycin-resistant Enterococcus faecium	B	Pfizer	2/11/2005	
249.	5/6/2005	Doryx Delayed-Release Tablets#	doxycycline	Treatment of infections	Labeling	• No new clinical studies submitted • PK data • Dosing information for new dosage form (to decrease esophagitis seen from capsules) • New dosage form	P	Warner Chilcott	NA	✓
250.	4/26/2005	Gemzar	gemcitabine	Refractory leukemia	Labeling	• Effectiveness in pediatric patients has not been demonstrated • Phase 1 trial in pediatric patients with refractory leukemia demonstrated a maximum tolerated dose; however, no meaningful clinical activity	B	Lilly	1/27/2005	

	Labeling Date♦	Trade Name	Generic or Proper (Biologics●) Name	Indication(s) Studied	Product Labeling	Labeling Changes	BPCA (B)/ PREA (P)/ Rule (R)	Sponsor	PE Granted Date	N N P S
						observed in a Phase 2 trial of gemcitabine in 22 patients with relapsed acute lymphoblastic leukemia and 10 patients with acute myelogenous leukemia • Toxicities observed were similar to those reported in adults				
251.	3/25/2005	Zofran	ondansetron	Prevention of chemotherapy -induced and postoperative induced nausea and vomiting	Labeling	• Established dosing for surgical patients down to 1 month from 2 years of age • Established dosing for cancer patients down to 6 months from 4 years of age • Surgical and cancer patients < 18 years tend to have a higher ondansetron clearance compared to adults leading to a shorter half-life in most pediatric patients • The clearance of ondansetron in patients 1- 4 months of age is slower and the half-life is approximately 2.5 fold longer than patients who are > 4 – 24 months of age • Patients < 4 months of age receiving this drug should be closely monitored • Additional information on dose, PK parameters, AE profile and safety	B	GlaxoSmith Kline	12/1/2004	
252.	3/11/2005	Rapamune	sirolimus	Prophylaxis of organ rejection in patients undergoing renal transplants	Labeling	• Safety and efficacy established in children 13 years or older judged to be at low to moderate immunologic risk • Safety was assessed in a controlled clinical trial in pediatric (<18 years of age) renal transplant recipients considered high immunologic risk. The use of Rapamune in combination with calcineurin inhibitors and corticosteroids was associated with an increased risk of deterioration of renal function, lipid abnormalities, and urinary tract infections • Safety and efficacy have not been established in pediatric patients less than 13 years old or in pediatric renal transplant recipients considered at high immunologic risk • Information on PK parameters, adverse events and safety	B	Wyeth	11/17/2004	
253.	3/11/2005	Xopenex HFA Inhalation Aerosol	levalbuterol	Treatment of bronchospasm in patients with reversible obstructive airway disease in children 4 years of age and older	Labeling	• Extended indication for use in children down from 6 years of age • Pediatric patients have a lower exposure to the drug than adults • Population PK model developed from patients down to 4 years of age • Effectiveness and safety established from studies in adults, adolescents (12 years of age and older) and children ages 4-11 years of age with asthma. • Deferred studies in patients < 4 years of age • New active ingredient	P	Sepracor	NA	
254.	3/3/2005	Clarinex D 24 Hour Extended Release	desloratadine*/pseudoephedrine	Relief of nasal and non-nasal symptoms of seasonal allergic	Labeling	• Two safety and effectiveness studies conducted in patients 12 years of age and older • PK study • Studies waived in children < 12 years of age	P	Schering	NA	

	Labeling Date♦	Trade Name	Generic or Proper (Biologics●) Name	Indication(s) Studied	Product Labeling	Labeling Changes	BPCA (B)/ PREA (P)/ Rule (R)	Sponsor	PE Granted Date	N N P S
		Tablets		rhinitis, including nasal congestion, in patients 12 years of age and older		• New active ingredient; new dosing regimen				
255.	2/18/2005	Celexa	citalopram	Major Depressive Disorder	Labeling	• Safety and effectiveness in the pediatric population have not been established • FDA required boxed warning for all antidepressants: Suicidality in Children and Adolescents - Antidepressants increased the risk of suicidal thinking and behavior (suicidality) in short-term studies in children and adolescents with Major Depressive Disorder (MDD) and other psychiatric disorders. Anyone considering the use of Celexa or any other antidepressant in a child or adolescent must balance this risk with the clinical need. Patients who are started on therapy should be observed closely for clinical worsening, suicidality, or unusual changes in behavior. Families and caregivers should be advised of the need for close observation and communication with the prescriber. Celexa is not approved for use in pediatric patients. (See Warnings and Precautions: Pediatric Use) Pooled analyses of short-term (4 to 16 weeks) placebo-controlled trials of 9 antidepressant drugs (SSRIs and others) in children and adolescents with major depressive disorder (MDD), obsessive compulsive disorder (OCD), or other psychiatric disorders (a total of 24 trials involving over 4400 patients) have revealed a greater risk of adverse events representing suicidal thinking or behavior (suicidality) during the first few months of treatment in those receiving antidepressants. The average risk of such events in patients receiving antidepressants was 4%, twice the placebo risk of 2%. No suicides occurred in these trials • Two placebo-controlled trials in 407 pediatric patients with MDD have been conducted with Celexa, and the data were not sufficient to support a claim for use in pediatric patients	B	Forest	7/12/2002	
256.	5/5/2004 and 2/18/2005	Effexor and Effexor XR	venlafaxine*	Major Depressive Disorder	Labeling	• Effectiveness in pediatric patients has not been established • FDA required boxed warning for all antidepressants: Suicidality in Children and Adolescents - Antidepressants increased the risk of suicidal thinking and behavior (suicidality) in short-term studies in children and adolescents with Major Depressive Disorder (MDD) and other psychiatric disorders. Anyone considering the use of Effexor or any other antidepressant in a child or adolescent must balance this risk with the clinical need. Patients who are started on therapy should be observed closely for clinical worsening, suicidality, or unusual changes in behavior. Families and caregivers should be advised of the need for close observation and communication with the prescriber. Effexor is not approved for use in pediatric patients. (See Warnings and Precautions: Pediatric Use) Pooled analyses of short-term (4 to 16 weeks) placebo-controlled trials of 9 antidepressant drugs (SSRIs and others) in children and adolescents with major depressive disorder (MDD), obsessive compulsive disorder (OCD), or other psychiatric disorders (a total of 24	B, P	Wyeth	12/2/2002	

	Labeling Date♦	Trade Name	Generic or Proper (Biologics●) Name	Indication(s) Studied	Product Labeling	Labeling Changes	BPCA (B)/ PREA (P)/ Rule (R)	Sponsor	PE Granted Date	N N P S
						trials involving over 4400 patients) have revealed a greater risk of adverse events representing suicidal thinking or behavior (suicidality) during the first few months of treatment in those receiving antidepressants. The average risk of such events in patients receiving antidepressants was 4%, twice the placebo risk of 2%. No suicides occurred in these trials. • 18% of Effexor XR treated patients (6-17 years) versus 3.6 % of placebo treated patients experienced a weight loss of at least 3.5 % in both MDD and the GAD studies • In an open-label study increases in weight were less than expected based on data from age and sex matched peers. The difference between observed weight gain was larger for children less than 12 years than for adolescents older than 12 years • During an 8 week placebo controlled GAD trial, Effexor XR treated patients ages 6-17 years grew an average of 0.3 cm, while placebo treated patients grew an average of 1 cm. In a 6 month open-label study, height increases that were less than expected based on data from age and sex matched pairs. The difference between observed and expected growth rates were larger for children less than 12 years than for adolescents older than 12 years • Decreased appetite observed in 10% of patients ages 6-17 years old receiving Effexor XR • Occurrence of blood pressure and cholesterol increases considered clinically relevant in pediatric patients similar to that observed in adults				
257.	9/28/2000 and 2/18/2005	Luvox	fluvoxamine	Treatment of obsessions and compulsions in patients with OCD	Labeling	• Determined that a dose adjustment (increased dose) may be necessary in adolescents and girls 8-11 years of age may require lower doses • FDA required boxed warning for all antidepressants: Suicidality in Children and Adolescents - Antidepressants increased the risk of suicidal thinking and behavior (suicidality) in short-term studies in children and adolescents with Major Depressive Disorder (MDD) and other psychiatric disorders. Anyone considering the use of fluvoxamine or any other antidepressant in a child or adolescent must balance this risk with the clinical need. Patients who are started on therapy should be observed closely for clinical worsening, suicidality, or unusual changes in behavior. Families and caregivers should be advised of the need for close observation and communication with the prescriber. Fluvoxamine is not approved for use in pediatric patients except for patients with obsessive compulsive disorder (OCD). (See Warnings and Precautions: Pediatric Use) Pooled analyses of short-term (4 to 16 weeks) placebo-controlled trials of 9 antidepressant drugs (SSRIs and others) in children and adolescents with major depressive disorder (MDD), obsessive compulsive disorder (OCD), or other psychiatric disorders (a total of 24 trials involving over 4400 patients) have revealed a greater risk of adverse events representing suicidal thinking or behavior (suicidality) during the first few months of treatment in those receiving antidepressants. The average risk of such events in patients receiving antidepressants was 4%, twice the placebo risk of 2%. No suicides occurred in these trials	B	Solvay	1/3/2000	

	Labeling Date♦	Trade Name	Generic or Proper (Biologics●) Name	Indication(s) Studied	Product Labeling	Labeling Changes	BPCA (B)/ PREA (P)/ Rule (R)	Sponsor	PE Granted Date	N N P S
						• The efficacy of fluvoxamine for the treatment of OCD was demonstrated in a 10-week multicenter placebo controlled study with 120 outpatients ages 8 to 17. In addition, 99 of these outpatients continued open-label fluvoxamine treatment for up to another one to three years, equivalent to 94 patient years				
258.	1/3/2003 and 2/18/2005	Prozac	fluoxetine-	Major Depressive Disorder (MDD) & Obsessive Compulsive Disorder (OCD)	Labeling	• Effectiveness established in patients 7-17 years of age for OCD • Effectiveness established in patients 8-17 years of age for MDD • FDA required boxed warning for all antidepressants: Suicidality in Children and Adolescents - Antidepressants increased the risk of suicidal thinking and behavior (suicidality) in short-term studies in children and adolescents with Major Depressive Disorder (MDD) and other psychiatric disorders. Anyone considering the use of Prozac or any other antidepressant in a child or adolescent must balance this risk with the clinical need. Patients who are started on therapy should be observed closely for clinical worsening, suicidality, or unusual changes in behavior. Families and caregivers should be advised of the need for close observation and communication with the prescriber. Prozac is approved for use in pediatric patients with MDD and obsessive compulsive disorder (OCD). (See Warnings and Precautions: Pediatric Use) Pooled analyses of short-term (4 to 16 weeks) placebo-controlled trials of 9 antidepressant drugs (SSRIs and others) in children and adolescents with major depressive disorder (MDD), obsessive compulsive disorder (OCD), or other psychiatric disorders (a total of 24 trials involving over 4400 patients) have revealed a greater risk of adverse events representing suicidal thinking or behavior (suicidality) during the first few months of treatment in those receiving antidepressants. The average risk of such events in patients receiving antidepressants was 4%, twice the placebo risk of 2%. No suicides occurred in these trials • Decreased weight gain has been observed in association with the use of fluoxetine, as with other SSRIs. In one 19-week clinical trial pediatric subjects treated with fluoxetine gained an average of 1.1cm less in height (p=0.004) and 1.1 kg less in weight (p=0.008) than those treated with placebo. Therefore, height and weight should be monitored periodically in pediatric patients treated with fluoxetine • Mania/hypomania led to discontinuation of 1.8% of fluoxetine treated patients vs. 0% of placebo controlled patients in the three placebo-controlled trials combined. Regular monitoring for the occurrence of mania/hypomania is recommended • Higher average steady state fluoxetine and norfluoxetine concentrations were observed in children than in adolescents. These differences were almost entirely explained by differences in weight • Separate dosing recommendations in lower weight children	B	Lilly	11/15/2000	
259.	2/18/2005	Zoloft	sertraline	Major Depressive Disorder and Obsessive	Labeling	• Safety and effectiveness in the pediatric population other than pediatric patients with OCD have not been established • FDA required boxed warning for all antidepressants: Suicidality in	B	Pfizer	2/1/2002	

	Labeling Date♦	Trade Name	Generic or Proper (Biologics●) Name	Indication(s) Studied	Product Labeling	Labeling Changes	BPCA (B)/ PREA (P)/ Rule (R)	Sponsor	PE Granted Date	N N P S
				Compulsive Disorder		Children and Adolescents • Antidepressants increased the risk of suicidal thinking and behavior (suicidality) in short-term studies in children and adolescents with Major Depressive Disorder (MDD) and other psychiatric disorders. Anyone considering the use of Zoloft or any other antidepressant in a child or adolescent must balance this risk with the clinical need. Zoloft is not approved for use in pediatric patients except for patients with obsessive compulsive disorder (OCD). (See Warnings and Precautions: Pediatric Use) Patients who are started on therapy should be observed closely for clinical worsening, suicidality, or unusual changes in behavior. Families and caregivers should be advised of the need for close observation and communication with the prescriber. Pooled analyses of short-term (4 to 16 weeks) placebo-controlled trials of 9 antidepressant drugs (SSRIs and others) in children and adolescents with major depressive disorder (MDD), obsessive compulsive disorder (OCD), or other psychiatric disorders (a total of 24 trials involving over 4400 patients) have revealed a greater risk of adverse events representing suicidal thinking or behavior (suicidality) during the first few months of treatment in those receiving antidepressants. The average risk of such events in patients receiving antidepressants was 4%, twice the placebo risk of 2%. No suicides occurred in these trials • Two placebo controlled trials in 373 pediatric patients with MDD have been conducted with Zoloft, and the data were not sufficient to support a claim for use in pediatric patients				
260.	1/12/2005	Paxil	paroxetine	Major Depressive Disorder	Labeling	• Safety and effectiveness in the pediatric population have not been established • FDA required boxed warning for all antidepressants: Suicidality in Children and Adolescents - Antidepressants increased the risk of suicidal thinking and behavior (suicidality) in short-term studies in children and adolescents with Major Depressive Disorder (MDD) and other psychiatric disorders. Anyone considering the use of Paxil or any other antidepressant in a child or adolescent must balance this risk with the clinical need. Patients who are started on therapy should be observed closely for clinical worsening, suicidality, or unusual changes in behavior. Families and caregivers should be advised of the need for close observation and communication with the prescriber. Paxil is not approved for use in pediatric patients. (See Warnings and Precautions: Pediatric Use) Pooled analyses of short-term (4 to 16 weeks) placebo-controlled trials of 9 antidepressant drugs (SSRIs and others) in children and adolescents with major depressive disorder (MDD), obsessive compulsive disorder (OCD), or other psychiatric disorders (a total of 24 trials involving over 4400 patients) have revealed a greater risk of adverse events representing suicidal thinking or behavior (suicidality) during the first few months of treatment in those receiving antidepressants. The average risk of such events in patients receiving antidepressants was 4%, twice the placebo risk of 2%. No suicides occurred in these trials • Three placebo-controlled trials in 752 pediatric patients with MDD have been conducted with Paxil, and the data were not sufficient to support a	B	Glaxo	6/27/2002	

	Labeling Date♦	Trade Name	Generic or Proper (Biologics●) Name	Indication(s) Studied	Product Labeling	Labeling Changes	BPCA (B)/ PREA (P)/ Rule (R)	Sponsor	PE Granted Date	N N P S
						claim for use in pediatric patients				
261.	1/12/2005	Remeron	mirtazapine	Major Depressive Disorder	Labeling	• Safety and effectiveness in the pediatric population have not been established • FDA required boxed warning for all antidepressants: Suicidality in Children and Adolescents - Antidepressants increased the risk of suicidal thinking and behavior (suicidality) in short-term studies in children and adolescents with Major Depressive Disorder (MDD) and other psychiatric disorders. Anyone considering the use of Remeron or any other antidepressant in a child or adolescent must balance this risk with the clinical need. Patients who are started on therapy should be observed closely for clinical worsening, suicidality, or unusual changes in behavior. Families and caregivers should be advised of the need for close observation and communication with the prescriber. Remeron is not approved for use in pediatric patients. (See Warnings and Precautions: Pediatric Use) Pooled analyses of short-term (4 to 16 weeks) placebo-controlled trials of 9 antidepressant drugs (SSRIs and others) in children and adolescents with major depressive disorder (MDD), obsessive compulsive disorder (OCD), or other psychiatric disorders (a total of 24 trials involving over 4400 patients) have revealed a greater risk of adverse events representing suicidal thinking or behavior (suicidality) during the first few months of treatment in those receiving antidepressants. The average risk of such events in patients receiving antidepressants was 4%, twice the placebo risk of 2%. No suicides occurred in these trials • Two placebo-controlled trials in 258 pediatric patients with MDD have been conducted with Remeron and the data were not sufficient to support a claim for use in pediatric patients	B	Organon	NA	
262.	1/12/2005	Serzone	nefazodone	Major Depressive Disorder	Labeling	• Safety and effectiveness in the pediatric population have not been established • FDA required boxed warning for all antidepressants: Suicidality in Children and Adolescents - Antidepressants increased the risk of suicidal thinking and behavior (suicidality) in short-term studies in children and adolescents with Major Depressive Disorder (MDD) and other psychiatric disorders. Anyone considering the use of Serzone or any other antidepressant in a child or adolescent must balance this risk with the clinical need. Patients who are started on therapy should be observed closely for clinical worsening, suicidality, or unusual changes in behavior. Families and caregivers should be advised of the need for close observation and communication with the prescriber. Serzone is not approved for use in pediatric patients. (See Warnings and Precautions: Pediatric Use) Pooled analyses of short-term (4 to 16 weeks) placebo-controlled trials of 9 antidepressant drugs (SSRIs and others) in children and adolescents with major depressive disorder (MDD), obsessive compulsive disorder (OCD), or other psychiatric disorders (a total of 24 trials involving over 4400 patients) have revealed a greater risk of adverse events representing suicidal thinking or behavior (suicidality) during the first few months of treatment in those receiving antidepressants. The average risk of such events in patients	B	Bristol-Myers Squibb	6/27/2002	

	Labeling Date♦	Trade Name	Generic or Proper (Biologics●) Name	Indication(s) Studied	Product Labeling	Labeling Changes	BPCA (B)/ PREA (P)/ Rule (R)	Sponsor	PE Granted Date	N N P S
						receiving antidepressants was 4%, twice the placebo risk of 2%. No suicides occurred in these trials • Two placebo-controlled trials in 286 pediatric patients with MDD have been conducted with Serzone, and the data were not sufficient to support a claim for use in pediatric patients				
263.	12/28/2004	Clolar	clofarabine	Relapsed or refractory acute lymphoblastic leukemia after at least two prior regimens	Labeling	• Labeling for patients 1 to 21 years old. This use is based on the induction of complete responses • Randomized trials demonstrating increased survival or other clinical benefit have not been conducted • Information on dose, PK parameters, and AE profihe	B	Genzyme	7/14/2004	
264.	12/22/2004	Pataday Ophthalmic Solution	olopatadine	Treatment of ocular itching associated with allergic conjunctivitis (itchy eyes) in children 3 years of age and older	Labeling	• Based on clinical trials that included patients down to 3 years of age. • New indication	P	Alcon	NA	
265.	12/17/2004	Augmentin ES-600 Powder for Oral Suspension#	amoxicillin; clavulanate	Treatment of acute bacterial sinusitis (ABS) (sinus infection) in children 3 months of age and older	Labeling	• No new pediatric studies • Effectiveness extrapolated from adult studies for Augmentin XR for ABS and from studies in pediatric patients with otitis media and by similar pharmacokinetics in pediatric patients • New indication	P	GlaxoSmith Kline	NA	✓
266.	12/16/2004	VisionBlue Ophthalmic Solution#	trypan blue	Aid in ophthalmic surgery by staining anterior capsule	Labeling	• Approved for use in all populations based on information from clinical trials in the literature • New drug	P	DORC International	NA	
267.	12/10/2004	Agrylin	anagrelide	Myeloproliferative disorders	Labeling	• An open-label study evaluated PK/PD but not efficacy. • Information on PK/PD profile, dosing, AEs, and safety in patients > 6 years to 17 years • No overall difference in dosing and safety were observed between pediatric and adult patients • Established recommended starting dose based on limited data. Dosage should be adjusted to the lowest effective dosage	B	Shire	5/25/2004	
268.	11/16/2004	Zomig	zolmitriptan	Migraine	Labeling	• Clinical trial evaluating zolmitriptan in pediatric patients ages 12 -17 years did not establish the safety and effectiveness when compared to placebo	B	AstraZeneca	12/18/2003	

	Labeling Date♦	Trade Name	Generic or Proper (Biologics●) Name	Indication(s) Studied	Product Labeling	Labeling Changes	BPCA (B)/ PREA (P)/ Rule (R)	Sponsor	PE Granted Date	N N P S
						• AEs observed in clinical trials were similar to those observed in clinical trials in adults.				
269.	10/21/2004	Concerta	methylphenidate	ADHD	Labeling	• Expanded labeling for 13-17 year olds including information on dose, PK parameters, and AE profile • Increase in age resulted in increased apparent oral clearance • For patients new to methylphenidate: higher maximum recommended dosage for adolescents compared to children 6-12 years of age • Data are inadequate to determine whether chronic use of stimulants in children may cause suppression of growth. Therefore, growth should be monitored during treatment • Safety and efficacy in children <6 years have not been established	B	Alza	12/4/2003	
270.	10/13/2004	Imitrex Nasal Spray	sumatriptan	Migraine	Labeling	• Five clinical trials evaluating oral sumatriptan in pediatric patients ages 12 -17 years did not establish the safety and effectiveness when compared to placebo • Postmarketing experience documents that serious AEs rarely reported in adults, including stroke, visual loss, and death have occurred in the pediatric population after use of subcutaneous, oral, and/ or nasal sumatriptan. • Since clinical data to determine the frequency of serious adverse events in pediatric patients who might receive injectable, oral, and/ or intranasal sumatriptan are not presently available, the use of sumatriptan in patients aged younger than 18 years is not recommended	B	Glaxo	2/18/2004	
271.	9/29/2004	Amlexanox Mucoadhesive Patch	amlexanox	Treatment of apthous ulcers in children 12 years of age and older	Labeling	• Approval based on monograph and previous studies for other indication • No new studies submitted • Studies in children birth – 12 years of age waived • New indication	P	Access Pharmaceuticals	NA	✓
272.	9/1/2004	Clarinex	desloratadine	Seasonal and perennial allergic rhinitis, and the symptomatic relief of pruritus, and hives	Labeling	• Indicated for seasonal allergic rhinitis down to 2 years of age. Extended age range down to 6 months for perennial allergic rhinitis and chronic idiopathic urticaria • Safety and effectiveness of tablets or syrup has not been established in pediatric patients less than 6 months of age • Information on dose, PK parameters, and AE profile in pediatric patients 6 months - 11 years of age	B	Schering	2/12/2003	
273.	8/19/2004	Vioxx	rofecoxib	Pauciarticular or polyarticular course Juvenile Rheumatoid Arthritis	Labeling	• Merck announced a voluntary worldwide withdrawal of Vioxx (rofecoxib) due to safety concerns on September 30, 2004. http://www.fda.gov/cder/drug/infopage/vioxx/PHA_vioxx.htm	B	Merck	2/18/2004	

	Labeling Date♦	Trade Name	Generic or Proper (Biologics●) Name	Indication(s) Studied	Product Labeling	Labeling Changes	BPCA (B)/ PREA (P)/ Rule (R)	Sponsor	PE Granted Date	N N P S
274.	8/13/2004	Ferrlecit	sodium ferric gluconate complex	Iron deficiency anemia in chronic hemodialysis patients receiving supplemental erythropoietin therapy	Labeling	• Safety and effectiveness established in pediatric patients 6 -15 years old • Patients <6 years of age not studied • Information on dose, PK parameters and AE profile	B, P	Watson	3/24/2004	
275.	7/30/2004	Claritin-D 12 Hour Extended -Release Tablets# Claritin-D 24 Hour Extended -Release Tablets#	loratadine*; pseudoephedrine	Temporary relief of nasal congestion due to the common cold in children 12 years of age and older OTC	Labeling	• Approval based on monograph and previous studies for other indication • No new studies submitted • Studies in children birth - 12 years of age waived • New indication	P	Schering-Plough	NA	✓
276.	6/24/2004	Camptosar	irinotecan	Refractory solid tumors	Labeling	• Effectiveness in pediatric patients has not been established • Adverse event profile from a Phase 2 trial with 170 children with refractory solid tumors comparable to that seen in adults; Grade 3-4 neutropenia experienced by 54 (31.8%) patients, neutropenia complicated by fever in 15 (8.8%) patients, Grade 3-4 diarrhea observed in 35 (20.6%) patients. • Accrual for phase 2 study with 21 children with previously untreated rhabdomyosarcoma halted due to high rate (23.6%) of progressive disease and early deaths (14%) • Adverse event profile seen in the 21 children different than that observed in adults; most significant Grade 3 or 4 adverse events were dehydration experienced by 6 patients (28.6%) associated with severe hypokalemia in 5 patients (23.8%) and hyponatremia in 3 patients (14.3%); in addition Grade 3-4 infection was reported in 5 patients (23.8%)(across all courses of therapy and irrespective of causal relationship) • PK parameters comparable to adults • Minimal accumulation of irinotecan and SN-38 (active metabolite) observed in children on daily dosing	B	Pfizer	3/10/2004	
277.	6/24/2004	TamiFlu	oseltamivir	Treatment of uncomplicated acute illness due to influenza infection in patients 1 year and older	Labeling	• Not recommended in pediatric patients less than 1 year of age because of uncertainties regarding the rate of development of the human blood-brain barrier and the unknown clinical significance of animal toxicology data for human infants	B	Roche	3/22/2004	
278.	6/21/2004	Codeprex	chlorpheniramine; codeine	Temporary relief of cough	Labeling	• Approval and age range based on monograph for antitussives and	P	Celltech Pharmaceut	NA	

	Labeling Date♦	Trade Name	Generic or Proper (Biologics●) Name	Indication(s) Studied	Product Labeling	Labeling Changes	BPCA (B)/ PREA (P)/ Rule (R)	Sponsor	PE Granted Date	NNPS
		Extended-Release Suspension#		associated with the common cold or inhaled irritants; temporary relief of symptoms of hay fever, other upper respiratory allergies, or allergic rhinitis in children 6 years of age and older OTC		antihistamine • No clinical studies submitted • Studies in children < 6 years of age deferred • New dosage form; new dosing regimen		icals		
279.	6/17/2004	Prevacid	lansoprazole	Symptomatic GERD in infants	Labeling	• Effectiveness was not established in a 4 week multicenter, double-blind, placebo-controlled study of patients 1 month and < 12 months of age • AE profile similar to that observed in adults • Information on PK parameters in neonates to < 1 year, and clinical studies	B	Tap	7/15/2008	
280.	6/2/2004	Humalog Injection	insulin lispro	Treatment of patients with diabetes mellitus for the control of hyperglycemia (high blood sugar) in children 3-11 years of age	Labeling	• Safety and effectiveness established from studies in patients 3-11 years of age • Dosing information added for external insulin pumps • New route of administration	P	Lilly	NA	
281.	5/25/2004	Axid	nizatidine	Esophagitis, and heartburn due to GERD	Labeling	• Indicated in pediatric patients 12 years and older • Information on dose, PK parameters, and AE profile	B	Reliant Pharms	NA	
282.	5/6/2004	Lidosite Topical System Kit	epinephrine; lidocaine	Topical local analgesia for superficial dermatological procedures in children 5 years of age and older	Labeling	• 505(b)(2) with clinical studies • Safety and effectiveness established in studies of pediatric patients 5-18 years of age • PK study in pediatric patients 6-15 years of age dosing regimen established in clinical trials • Studies in patients 0-5 years of age deferred • New dosage form; new route of administration	P	Vyteris	NA	
283.	4/29/2004	Mucinex DM	guaifenesin; dextromethorpha	Expectorant and cough	Labeling	• 505(b)(2) approved with no pediatric information	P	Adams Respiratory	NA	

	Labeling Date♦	Trade Name	Generic or Proper (Biologics●) Name	Indication(s) Studied	Product Labeling	Labeling Changes	BPCA (B)/ PREA (P)/ Rule (R)	Sponsor	PE Granted Date	N N P S
		Extended -release Tablet#	n	suppressant in children 12 years of age and older		• Age range based on monograph • Do not use in children under 12 years of age • studies waived in children < 12 years of age due to safety concerns • New dosage form		Therapeutics		
284.	4/21/2004	Advair Diskus	fluticasone/ salmeterol	Asthma	Labeling	• Extended indication from 12 years down to 4 years of age	P	GlaxoSmith Kline	NA	
285.	4/14/2004	Detrol LA	tolterodine	Urinary frequency and urge incontinence due to neurogenic conditions	Labeling	• Efficacy in pediatric population has not been demonstrated • The dose-plasma concentration relationship is linear in patients from 11 to 15 years • Parent/ metabolite ratios differed according to CYP2D6 metabolizer status • 710 pediatric patients ages 5 -10 years with urinary frequency and urge incontinence were studied in 2 randomized placebo controlled trials. Urinary tract infections were higher in patients treated with Detrol LA (6.6%) compared to placebo (4.5%) • Aggressive, abnormal and hyperactive behavior and attention disorders occurred in 2.9% of children treated with Detrol LA compared to 0.9% treated with placebo	B	Pfizer	1/5/2004	
286.	4/14/2004	Trusopt	dorzolamide	Reduction in intraocular pressure	Labeling	• Safety and IOP-lowering effects have been demonstrated in pediatric patients • Adverse event profile was comparable to that seen in adults	B	Merck	1/5/2004	
287.	4/1/2004	Corlopam	fenoldopam	Indicated for the in-hospital, short-term reduction in blood pressure	Labeling	• Indicated for the in-hospital, short-term (up to 4 hours) reduction in blood pressure in pediatric patients <1 month (at least 2 kg) to 12 years of age • Information on PK, dose and AE profile • Clinical studies did not include patients 12 – 16 years of age	B	Hospira	NA	
288.	3/31/2004	Zemplar	paricalcitol	Secondary hyperparathyroidism associated with end stage renal disease	Labeling	• Safety and effectiveness were examined in a 12 week randomized, double-blind, placebo-controlled study of 29 pediatric patients aged 5-19 years old with end stage renal disease on hemodialysis; information • Primary efficacy analysis revealed 9 of 15 patients in Zemplar group had 2 consecutive 30 % decreases from baseline intact PTH compared with 3 of 14 patients in placebo group • No patients in either group developed hypercalcemia (defined as at least one calcium value >11.2 mg/dL) during study	B	Abbott	12/8/2003	
289.	3/25/2004	Cipro	ciprofloxacin	Complicated UTI and pyelonephritis	Labeling	• Indicated for the treatment of complicated urinary tract infections (cUTIs) and pyelonephritis in pediatric patients 1 – 17 years of age • Not drug of first choice due to increased adverse events compared to controls including events related to joints and/or surrounding tissues	B	Bayer	12/18/2003	

	Labeling Date♦	Trade Name	Generic or Proper (Biologics●) Name	Indication(s) Studied	Product Labeling	Labeling Changes	BPCA (B)/ PREA (P)/ Rule (R)	Sponsor	PE Granted Date	N N P S
						• Information on PK and dose in pediatric patients 1 – 17 years of age • The most frequent adverse events observed within 6 weeks of treatment initiation during the cUTI clinical trial were gastrointestinal 15% compared to 9% and musculoskeletal 9.3% compared to 6% in ciprofloxacin-treated compared to control-treated patients, respectively				
290.	3/19/2004	Viracept	nelfinavir	HIV-1	Labeling	• Safety and effectiveness established in patients 2 – 13 years of age • New twice daily dosing regimen and modified three times daily dosing for pediatric patients > 2 years • A reliably effective dose not established in patients <2 years of age • PK information in pediatric patients from birth to 13 years of age • Highly variable drug exposure is a significant problem in pediatric patients • Adverse event profile was similar to that for adults	B, P	Pfizer	9/4/2003	
291.	3/15/2004	Glucovance	glyburide/ metformin	Type 2 Diabetes Mellitus	Labeling	• As studied in active-controlled, double blind trial in pediatric patients (9 – 16 years of age), Glucovance was not statistically superior to either metformin or glyburide in reducing HbA1C from baseline • No unexpected safety findings	B	Bristol-Myers Squibb	10/8/2003	
292.	3/11/2004	Cozaar	losartan	Hypertension	Labeling	• Antihypertensive effects established in hypertensive patients 6-16 years of age • Not recommended for pediatric patients less than 6 years or with glomerular filtration rate < 30mL/ min/1.73 m2 due to no data • Information on PK and dose in pediatric patients 6-16 years of age. • No relevant differences between the AE profile for pediatric patients compared to reported AEs for adults • Information on preparation of a suspension	B	Merck	3/20/2002	
293.	3/8/2004	Ultiva	remifentanil	Maintenance of anesthesia	Labeling	• Safety and efficacy for the maintenance of anesthesia established from birth to 1 year of age • Recommended dosing guidelines for maintenance of anesthesia for patients from birth to 2 months • The clearance rate observed in neonates was highly variable – approximately 2 times higher than young healthy adults • Individual doses for each patient should be carefully titrated	B, P	Abbott	3/15/2000	
294.	3/5/2004	Arava	leflunomide	Polyarticular Juvenile Rheumatoid Arthritis	Labeling	• Safety and efficacy in pediatric patients with polyarticular JRA have not been fully evaluated • 94 patients with polyarticular JRA were studied in a double-blind active controlled trial (1:1 randomization); approximately 68% of pediatric patients receiving Arava versus 89% receiving active comparator demonstrated improvement on the primary endpoint by week 16	B, P	Aventis	11/10/2003	

	Labeling Date♦	Trade Name	Generic or Proper (Biologics●) Name	Indication(s) Studied	Product Labeling	Labeling Changes	BPCA (B)/ PREA (P)/ Rule (R)	Sponsor	PE Granted Date	NNPS
						• Pediatric patients with a body weight ≤ 40 kg have a reduced clearance relative to adult rheumatoid arthritis patients • Information on PK of M1, the active metabolite responsible for in vivo activity in children 3-17 years old • Most common adverse events in 74 polyarticular JRA patients 3-17 years old included abdominal pain, diarrhea, nausea, vomiting, oral ulcers, upper respiratory tract infections, alopecia, rash, headache, and dizziness • 14 of the 74 patients experienced ALT and/or AST elevations; 5/14 were between 3 and 8 fold the upper limit of normal				
295.	3/2/2004	Lotensin	benazepril	Hypertension	Labeling	• Information on dose, PK in pediatric patients 6-16 years of age • Not recommended for pediatric patients less than 6 years or with glomerular filtration rate < 30mL/min/1.73 m2 due to insufficient data • Infants below the age of 1 year should not be given ACE inhibitors due to concerns over possible effects on kidney development • The clearance rate was substantially higher in hypertensive children and adolescents than that of healthy adults • The terminal half life (t1/2) in pediatric patients was one third of that observed in adults • Adverse event profile in pediatric patients was similar to that seen in adults • Information on preparation of a suspension	B	Novartis	7/2/2003	
296.	2/27/2004	Myfortic Delayed-Release Tablets	mycophenolic acid	Prevention of organ rejection in patients receiving allogeneic renal transplants in children 5-16 years of age with stable renal transplants	Labeling	• Approval based on extrapolation of safety and effectiveness in adult patients • One PK study with information down to 5 years of age • Waived studies in birth to 10 years because there are too few children to study. • New active ingredient	P	Novartis	NA	
297.	2/24/2004	Children's Advil Allergy Sinus Suspension	chlorpheniramine; ibuprofen*; pseudoephedrine*	Symptoms of allergic rhinitis (runny nose) and the common cold in children 6 years of age and older	Labeling	• Effectiveness extrapolated from adult studies • Bioequivalence studies in healthy adults • PK and safety studies in children 6 to 12 years of age • New dosage form	P	Wyeth Consumer Healthcare	NA	
298.	1/15/2004	Zithromax Tablets	azithromycin	Treatment of acute bacterial sinusitis (sinus	Labeling	• Effectiveness extrapolated from adult sinusitis studies and from pediatric acute otitis media studies	P	Pfizer	NA	

	Labeling Date♦	Trade Name	Generic or Proper (Biologics●) Name	Indication(s) Studied	Product Labeling	Labeling Changes	BPCA (B)/ PREA (P)/ Rule (R)	Sponsor	PE Granted Date	N N P S
				infection) in patients 6 months of age and older		• Clinical studies conducted in pediatric patients 3 years to 16 years of age to determine PK and safety for oral suspension • Safety and effectiveness in patients under 6 months of age have not been established • Side effects seen in pediatric patients were comparable to those seen in adults, with different incidence rates for the dosage regimens recommended in pediatric patients • Dosing regimen established • Partial waiver < 6 months of age because too few patients to study • New indication				
299.	1/08/2004	Norvasc	amlodipine	Hypertension		• Information on dose, PK in pediatric patients 6-17 years of age • Adverse event profile in pediatric patients was similar to that seen in adults	B	Pfizer	11/27/2001	
300.	12/12/2003	Xenical	orlistat	Obesity management	Labeling	• Use in 12-16 year olds is supported by studies in adults with additional data from a 54 week safety and efficacy study in obese adolescent patients. • Since orlistat can reduce absorption of fat soluble vitamins, all patients should take a daily multivitamin supplement containing fat soluble vitamins. • Adverse event profile in adolescent patients was similar to that seen in adults	B	Roche	9/12/2003	
301.	12/10/2003	Ertaczo Cream	sertaconazole	Treatment of interdigital tinea pedis (athlete's foot) in children 12 years of age and older	Labeling	• Safety and effectiveness established in clinical trials involving adolescent patients • Studies in patients less than 12 years of age waived because there are too few children with the disease to study • New drug	P	Mylan	NA	
302.	12/2/2003	Malarone	atovaquone/ proguanil	Prophylaxis and treatment of malaria	Labeling	• Safety and effectiveness established down to ≥ 11kg • Information on dose, efficacy, PK parameters and AE profile • Elimination half-life is shorter in pediatric patients (1 to 2 days) than in adults (2 to 3 days) • Attributable AE's occurring in ³ 5% of the pediatric patients were vomiting (10%) and pruritus (6%)	B	GlaxoSmith Kline	8/6/2003	
303.	10/16/2003	Elestat Ophthalmic Solution	epinastine	Prevention of itching associated with allergic conjunctivitis in children 3 years of age	Labeling	• Based on effectiveness and safety studies that included children down to 10 years of age • Partial waiver for children < 3 years of age because the condition does not exist in the age group • New drug	P	Allergan	NA	

	Labeling Date♦	Trade Name	Generic or Proper (Biologics●) Name	Indication(s) Studied	Product Labeling	Labeling Changes	BPCA (B)/ PREA (P)/ Rule (R)	Sponsor	PE Granted Date	N N P S
				and older						
304.	10/10/2003	Denavir Cream	penciclovir	Treatment of recurrent herpes labialis (cold sores) in children 12 years of age and older	Labeling	• Extended indication down from 18 years of age to 12 years of age • Effectiveness extrapolated from adult studies • Safety study in patients 12-17 years of age • Pediatric submission	P	Novartis	NA	
305.	9/30/2003	Floxin Otic Solution	ofloxacin	Treatment of otitis externa (outer ear infection) in children 6 months of age and older	Labeling	• Dosing change from 2 times daily to 1 time daily for 7 days based on effectiveness and safety studies that included pediatric patients • New dosing regimen	P	Daiichi	NA	
306.	8/1/2003	Fludara	fludarabine	Refractory acute leukemia and solid tumors	Labeling	• Fludarabine was evaluated in 62 pediatric patients and the data were insufficient to establish efficacy in any childhood malignancy	B	Berlex	4/3/2003	
307.	12/28/2001; 7/29/2003	Rebetron ; Rebetrol	ribavirin/intron a; ribavirin	Chronic hepatitis C	Labeling	• Labeling for 3 years to 16 years • There are no safety and efficacy data on treatment for longer than 48 weeks in pediatric patients • Pharmacokinetic information on patients 5 to 16 years with chronic hepatitis C virus infection • Increased incidence of suicidal ideation or attempts (2.4% versus 1%) among pediatric patients compared to adult patients • Decrease in rate of linear growth (mean percentile assignment decrease of 9%) and in rate of weight gain (mean percentile assignment decrease of 13%) during 48 weeks of treatment; a general reversal was noted during the 24 week post treatment period • Patients with viral genotype 1, had a lower response rate to combination therapy compared to patients with genotype non-1, 36% versus 81% • In general, the adverse event profile in the pediatric population was similar to that observed in adults • New oral suspension developed	B	Schering	5/9/2001	
308.	7/18/2003	Ciprodex Sterile Otic Suspension	ciprofloxacin*; dexamethasone	Treatment of acute otitis media in patients with tympanostomy tubes (inner ear infection) in children 6 months of age and older treatment of acute otitis externa (outer	Labeling	• Over 700 pediatric patients in safety and effectiveness studies to support both indications • Pediatric dosing information added • New dosage form	P	Alcon	NA	

	Labeling Date♦	Trade Name	Generic or Proper (Biologics●) Name	Indication(s) Studied	Product Labeling	Labeling Changes	BPCA (B)/ PREA (P)/ Rule (R)	Sponsor	PE Granted Date	N N P S
				ear infection) in children 6 months of age and older						
309.	7/1/2003	Zestril	lisinopril	Hypertension	Labeling	• Labeling for 6-16 years of age • Not recommended for pediatric patients less than 6 years or with glomerular filtration rate < 30mL/min/1.73m2 • Information on dose, efficacy and pharmacokinetics • No relevant differences were identified between adverse experience profile for pediatric patients and that previously reported for adult patients • Information on preparation of a suspension	B	AstraZeneca	11/19/2001	
310.	5/29/2003	Prinivil	lisinopril	Hypertension	Labeling	• Labeling for 6-16 years of age • Not recommended for pediatric patients with glomerular filtration rate < 30ml/min/1.73m2 • Information on dose, efficacy and pharmacokinetics • No relevant differences were identified between adverse experience profile for pediatric patients and that previously reported for adult patients • Information on preparation of a suspension	B	Merck	11/19/2001	
311.	5/27/2003	Monopril	fosinopril	Hypertension	Labeling	• New data from a double-blind study in 252 patients 6-16 years of age • New recommended dose in children weighing more than 50kg • New Information on PK parameters • An appropriate dosage strength is not available for children weighing less than 50kg	B	Bristol-Myers Squibb	1/27/2003	
312.	5/23/2003	Duocaine Injection #	bupivacaine; lidocaine	Local regional anesthesia for ophthalmologic surgery by peripheral nerve block techniques in children 12 years of age and older	Labeling	• Safety and effectiveness extrapolated from existing clinical database • Safety and effectiveness not established in patients < 12 years of age • Partial waiver 0-12 years of age because general anesthesia is preferred in that population • New active ingredient	P	Amphastar	NA	
313.	5/20/2003	Duragesic	fentanyl	Management of chronic pain	Labeling	• Safety evaluated in three open-label trials in 291 patients 2 years through 18 years of age with chronic pain • New Warning: Duragesic should be administered to children only if they are opioid-tolerant and age 2 years or older • New information on pharmacokinetics, dosage and administration and patient information • Precaution to guard against accidental ingestions by children	B	Alza	1/29/2003	

	Labeling Date♦	Trade Name	Generic or Proper (Biologics●) Name	Indication(s) Studied	Product Labeling	Labeling Changes	BPCA (B)/ PREA (P)/ Rule (R)	Sponsor	PE Granted Date	N N P S
						• Adverse Events: no apparent pediatric-specific risk associated with Duragesic use in children as young as 2 years old when used as directed. Most common adverse events were fever (35%), vomiting (33%), and nausea (24%)				
314.	5/12/2003	Allegra	fexofenadine	Allergic rhinitis	Labeling	• Three clinical safety studies in 845 children with allergic rhinitis are described in the label	B	Aventis	1/27/2003	
315.	4/15/2003	Ditropan & Ditropan XL	oxybutynin-	Detrusor Overactivity Associated with a Neurological Condition	Labeling	Ditropan • Additional information on dose and PK parameters • Precautions section of label updated Ditropan XL • Safety and effectiveness established down to 6 years of age	B	Johnson & Johnson	2/8/2002	
316.	4/15/2003	Methylin Chewable Tablets#	methylphenidate	Treatment of Attention-Deficit Hyperactivity Disorder in children 6 years of age and older treatment of narcolepsy in children 6 years of age and older	Labeling	• Bioequivalence studies in adults • New dosage form	P	Mallinckrodt	NA	
317.	4/15/2003	Vigamox	moxifloxacin-	Bacterial Conjunctivitis	Labeling	• Safety and effectiveness established down to 1 year of age	B	Alcon	1/10/2003	
318.	3/11/2003	Temodar	temozolomide	Recurrent CNS tumors	Labeling	• Temozolomide effectiveness in children has not been demonstrated • New data from 2 open-label Phase 2 studies in pediatric patients 3-18 years of age. In one study there were 29 patients with recurrent brain stem glioma and 34 patients with recurrent high grade astrocyoma. In a second study there were 122 patients enrolled with various types of tumors; 113 CNS tumors and 9 non-CNS tumors. • The temozolomide toxicity profile in children is similar to adults	B	Schering	11/20/2002	
319.	2/26/2003	Pulmicort	budesonide	Maintenance and Prophylaxis of Asthma	Labeling	• Safety information in pediatric patients 6 to 12 months of age • A dose dependent effect on growth was observed in the 12-week trial which supports the finding that the use of Pulmicort Respules in infants 6 to 12 months of age may result in systemic effects and is consistent	B	AstraZeneca	11/12/2002	

	Labeling Date♦	Trade Name	Generic or Proper (Biologics●) Name	Indication(s) Studied	Product Labeling	Labeling Changes	BPCA (B)/ PREA (P)/ Rule (R)	Sponsor	PE Granted Date	N N P S
						with the findings of growth suppression in other studies with inhaled corticosteroids • Pneumonia was observed more frequently in patients treated with Pulmicort Respules than in patients treated with placebo				
320.	1/17/2003	Lamictal	lamotrigine	Adjunctive therapy for partial seizures	Labeling	• Extended indication from adults to pediatric patients ≥ 2 years • Patients aged 2 - 18 years had clearance influenced predominantly by total body weight and concurrent antiepileptic drug (AED) therapy. The oral clearance was higher, on a body weight basis, in pediatric patients than in adults • Because of increased clearance in pediatrics, maintenance doses in patients weighing < 30 kg may need an increase of as much as 50% based upon clinical response • Evidence shows that the inclusion of VPA in a multi-drug regimen increases the risk of serious, potentially life-threatening rash in pediatric patients • Approximately 11.5% of the 1,081 pediatric patients who received the drug as adjunctive therapy in clinical trials discontinued treatment because of an AE	B	GlaxoSmith Kline	2/14/2007	
321.	1/13/2003	Busulfex	busulfan	Part of a conditioning regimen administered prior to hematopoietic progenitor cell transplantation for a variety of malignant hematologic or non-malignant diseases	Labeling	• The population pharmacokinetic estimates of busulfan for clearance and volume of distribution were determined in an open-label, uncontrolled PK study in 24 pediatric patients 5 months to 16 years who received busulfan as part of a conditioning regimen administered prior to hematopoietic progenitor cell transplantation for a variety of malignant hematologic or non-malignant diseases • Suggested dosing regimen	B	Orphan Medical	3/12/2002	
322.	12/31/2002	Singulair Oral Granules*, Tablets*, and Chewable Tablets*	montelukast	Seasonal allergic rhinitis in children 2 years of age and older	Labeling	• Effectiveness extrapolated from studies in patients 15 years of age and older and supported with one pediatric safety trial in patients 2-14 years of age • New indication	P	Merck	NA	
323.	12/30/2002	Zovirax Cream	acyclovir	Treatment of herpes labialis (cold sores) in	Labeling	• Adolescents 12-17 years of age included in clinical safety studies. • dosing regimen established waived in children < 12 years of age because rarely seen in that population	P	GlaxoSmith Kline	NA	

	Labeling Date♦	Trade Name	Generic or Proper (Biologics●) Name	Indication(s) Studied	Product Labeling	Labeling Changes	BPCA (B)/ PREA (P)/ Rule (R)	Sponsor	PE Granted Date	N N P S
				children 12 years and older		• New dosage form				
324.	12/26/2002	Relpax	eletriptan	Migraine	Labeling	• Summary pending	P	Pfizer	NA	
325.	12/19/2002	Zyvox	linezolid	Nosocomial pneumonia, community-acquired pneumonia, complicated and uncomplicated skin and skin structure infections, and vancomycin-resistant infections caused by susceptible strains	Labeling	• Extended age range down to birth for nosocomial pneumonia, community-acquired pneumonia, complicated skin and skin structure infections and vancomycin-resistant infections. Safety and efficacy extrapolated from studies in adults and supported by PK and comparator-controlled studies in patients from birth to 11 years • Extended age range down to 5 years of age for uncomplicated skin and skin structure infections based upon a comparator-controlled study in 5 to 17 year olds • Clearance of linezolid varies as a function of age; As age of pediatric patients increases, clearance gradually decreases, and by adolescence mean clearance values approach those observed in adults • Pediatric patients exhibit wider variability in clearance and systemic exposure (AUC) compared with adults • New every 8 hours dosing regimen for pediatric patients birth to 11 years of age and every 12 hours dosing regimen for pediatric patients 12 years and older • Information on PK parameters, AE profile, laboratory changes, dosing, and clinical studies	B	Pfizer	2/11/2005	
326.	12/4/2002	Centany Ointment 2%	mupirocin	Treatment of impetigo in children 2 months of age and older	Labeling	• New dosage form: ointment that differed from already approved ointment with pediatric clinical trials to demonstrate equivalence	P	Clay-Park Labs	NA	
327.	11/26/2002	Strattera	atomoxetine	Attention-Deficit Hyperactivity Disorder	Labeling	• Safety and effectiveness established down to 6 years of age • It is unknown whether final adult height or weight is affected by treatment. Patients on long-term treatment should be monitored • The effectiveness of atomoxetine beyond 9 weeks and safety beyond 1 year in pediatric patients, has not been systematically evaluated in controlled trials	B	Lilly	12/18/2001	
328.	11/5/2002	Navelbine	vinorelbine	Malignant tumors	Labeling	• New data from a single-arm study in 46 patients with recurrent solid malignant tumors, including rhabdomyosarcoma /undifferentiated sarcoma, neuroblastoma, and CNS tumors, at doses similar to those used in adults showed no meaningful clinical activity	B	GlaxoSmith Kline	8/15/2002	
329.	10/29/2002	Pravachol	pravastatin	Heterozygous Familial Hypercholesterolemia	Labeling	• New indication in boys and girls 8-18 years of age	B	Bristol-Myers Squibb	7/10/2002	
330.	10/21/2002	Zyrtec	cetirizine	Perennial Allergic	Labeling	• Extended the age range from 2 years to 6 months	B	Pfizer	3/13/2002	

	Labeling Date♦	Trade Name	Generic or Proper (Biologics●) Name	Indication(s) Studied	Product Labeling	Labeling Changes	BPCA (B)/ PREA (P)/ Rule (R)	Sponsor	PE Granted Date	N N P S
				Rhinitis & Chronic Urticaria		• Information on dose, PK parameters and AE profile				
331.	10/18/2002	Lipitor	atorvastatin	Heterozygous Familial Hypercholesterolemia	Labeling	• New indication in adolescent boys and girls (post-menarche) 10-17 years of age	B	Pfizer	2/22/2002	
332.	10/18/2002	Zocor	simvastatin	Heterozygous Familial Hypercholesterolemia	Labeling	• New indication in adolescent boys and girls (at least one year post-menarche) 10-17 years of age	B	Merck	2/22/2002	
333.	10/8/2002	Epivir	lamivudine-	HIV	Labeling	• Lamivudine clearance substantially reduced in 1-week-old neonates relative to pediatric patients >3 months of age	B	GlaxoSmith Kline	9/22/2000	
334.	8/30/2002	Nolvadex	tamoxifen	McCune-Albright Syndrome	Labeling	• A study in 28 female patients aged 2-10 years with McCune-Albright Syndrome and precocious puberty did not demonstrate safety and effectiveness. Long term effects have not been established • Mean uterine volume increased after 6 months of therapy and doubled at end of 1-year study	B	AstraZeneca	5/16/2002	
335.	8/26/2002	DUAC Topical Gel	clindamycin 1%/benzoyl peroxide 5%	Acne	Labeling	• Added combination topical treatment for mild to moderate acne	R	Stiefel Laboratories	NA	
336.	7/26/2002	Singulair	montelukast	Prophylaxis and chronic treatment of asthma	Labeling	• Safety and effectiveness established in patients 12 months to 5 years of age • Information on dose, PK parameters and AE profile in patients 12-23 months and 2-5 years • New 4mg chewable tablet and 4mg oral granule formulations developed. The chewable tablets contain aspartame whereas the oral granule formulation does not	B	Merck	12/10/2001	
337.	7/17/2002	Nasonex -nasal Elocon-topical	mometasone-	Nasonex - Perennial and seasonal allergic rhinitis Elocon - Relief of inflammatory and pruritic manifestations of corticosteroid dermatose	Labeling - Nasonex Labeling - Elocon Cream Labeling - Elocon Ointment Labeling - Elocon Lotion	• Nasonex Nasal Spray • Extended age range from 3 years down to 2 years • In a clinical study in which pediatric patients 2-5 years were treated with mometasone nasal spray for up to 42 consecutive days, no significant effect on adrenal function was found • Upper respiratory tract infection was more common with Nasonex (2/28) compared to placebo (0/28) • Elocon Cream & Ointment • Evidence of HPA axis suppression in pediatric patients 6-23 months of age • Outlined local AE's as well as skin atrophy in pediatric patients 6-23 months of age • Approved down to 2 years of age as in previous labeling • Elocon Lotion • Safety and effectiveness have not been established in pediatric patients	B	Schering	11/7/2001	

	Labeling Date♦	Trade Name	Generic or Proper (Biologics●) Name	Indication(s) Studied	Product Labeling	Labeling Changes	BPCA (B)/ PREA (P)/ Rule (R)	Sponsor	PE Granted Date	N N P S
						below 12 years of age and use <12 year old is not recommended • Should not be used for the treatment of diaper dermatitis				
338.	7/12/2002	Prilosec	omeprazole-	Gastroesophageal reflux and erosive esophagitis	Labeling	• Safety and effectiveness established in pediatric patients 2-16 years of age • Information on dose, PK parameters, exposure/response and AE profile	B	AstraZeneca	5/1/2001	
339.	6/26/2002	Clarinex RediTabs Orally Disintegrating Tablets	desloratadine	Allergic rhinitis and chronic ideopathic urticaria	Labeling	• Approved for use down to 12 years of age; new formulation	R	Schering	NA	
340.	6/6/2002	Pepcid	famotidine-	Gastroesophageal reflux	Labeling	• Labeling for patients less than 1 year of age including information on dose, PK/PD parameters and AE profile • Lower dose recommended in patients <3 months of age • Pediatric patients 0-3 months of age had clearance values 2 to 4-fold less than those in older patients and adults • In a clinical study of 35 pediatric patients <1 year of age, agitation was observed in 5 patients on famotidine and resolved upon discontinuation of the drug	B	Merck	11/21/2000	
341.	6/5/2002	Ritalin LA Capsules	methylphenidate	Attention Deficit Hyperactivity Disorder	Labeling	• Approved for use in 6-12 years of age; once a day dose in the morning	R	Novartis	NA	
342.	5/2/2002	Accutane	isotretinoin	Severe recalcitrant nodular acne	Labeling	• Safety and effectiveness information on pediatric patients 12-17 years of age • Identified an increased incidence of back pain, arthralgia and myalgia in pediatric patients • New General Precautions subsection- caution when prescribing Accutane to pediatric patients with disorders of bone metabolism, such as osteoporosis and osteomalacia • Adolescents who participate in sports with a repetitive impact may be at increased risk for bone related injuries • In an open-label study of pediatric patients (n=217) given a single course of therapy, 16 (7.9%) had decreases in lumbar spine bone mineral density (BMD) >4% (adjusted for body mass index); 21 (10.6%) patients had decreases in total hip BMD >5% (adjusted for body mass index)	B	Hoffman La-Roche	6/12/2001	
343.	4/18/2002	Advil Cold Suspension	ibuprofen/ pseudoephedrine	Temporary relief of nasal and sinus congestion, headache,	Labeling	• Information on the over-the-counter use in pediatric patients 2 to 11 years of age	B	Whitehall	9/19/2001	

	Labeling Date♦	Trade Name	Generic or Proper (Biologics●) Name	Indication(s) Studied	Product Labeling	Labeling Changes	BPCA (B)/ PREA (P)/ Rule (R)	Sponsor	PE Granted Date	NNPS
				stuffy nose, sore throat, minor aches and pains, and fever						
344.	4/1/2002	Videx	didanosine	HIV infection	Labeling	• Safety and effectiveness established down to 2 weeks	B	Bristol-Myers Squibb	8/13/2001	
345.	3/29/2002	Zerit	stavudine	HIV infection	Labeling	• Safety and effectiveness established down to birth • Established a dose for newborns from birth to 13 days	B	Bristol-Myers Squibb	8/13/2001	
346.	2/14/2002	Mevacor	lovastatin	Heterozygous Familial Hypercholesterolemia	Labeling	• New indication in adolescent boys and girls (at least one year post-menarche) 10-17 years of age	B	Merck	7/17/2001	
347.	2/8/2002	Acular & Acular PF	ketorolac	Relief of ocular itching due to seasonal allergic rhinitis and postoperative inflammation after cataract extraction	Labeling	• Safety and effectiveness established down to 3 years; previously approved down to 12 years	B	Allergan	9/6/2001	
348.	2/8/2002	Clarinex Tablets	desloratadine	Perennial allergic rhinitis	Labeling	• Approved down to 12 years of age	R	Schering	NA	
349.	2/8/2002	Clarinex Tablets	desloratadine	Relief of pruritis/hives in patients with chronic idiopathic urticaria	Labeling	• Approved down to 12 years of age	R	Schering	NA	
350.	1/30/2002	Xopenex Inhalation Solution	levalbuterol	Treatment and prevention of bronchspasm	Labeling	• Approved down to 6 years of age; recommended dose is 0.31mg TID for patients 6-11 years of age	R	Sepracor	NA	
351.	1/25/2002	Daypro	oxaprozin	Relief of signs and symptoms of Juvenile Rheumatoid Arthritis	Labeling	• New indication in 6 years -16 years	B	Searle	12/6/1999	
352.	5/1/2003 & 1/18/2002	Flonase Nasal Spray & Cutivate Ointment	fluticasone-	Flonase - nasal symptoms of seasonal and perennial allergic and nonallergic rhinitis	Labeling -Flonase Labeling - Cutivate	Flonase • New data from 1-year placebo-controlled clinical growth study in pediatric patients 3-9 years of age; no statistically significant effect on growth was noted compared to placebo. No evidence of clinically relevant changes in HPA axis function or bone mineral density was observed as assessed by 12-hour urinary cortisol excretion and dual-	B	GlaxoSmith Kline	2/25/2003	

	Labeling Date♦	Trade Name	Generic or Proper (Biologics●) Name	Indication(s) Studied	Product Labeling	Labeling Changes	BPCA (B)/ PREA (P)/ Rule (R)	Sponsor	PE Granted Date	N N P S
				Cutivate Ointment - corticosteroid-responsive dermatoses		energy x-ray absorptiometry, respectively. Cutivate • Indicated for use only in adult patients • In a study of 35 pediatric patients treated for atopic dermatitis, subnormal adrenal function was observed with cosyntropin stimulation testing				
353.	12/21/2001	Clarinex Tablets	desloratadine	Seasonal allergic rhinitis	Labeling	• Approved down to 12 years of age	R	Schering	NA	
354.	12/20/2001	Alphagan	brimonidine	Prevention of post-operative IOP elevations	Labeling	• Safety and effectiveness established down to 2 years • Somnolence in patients 2 to 6 years (50-83%) versus patients 7 years of age or older (25%)	B	Allergan	10/10/2001	
355.	12/13/2001	Elidel	pimecrolimus	Treatment of mild/moderate atopic dermatitis	Labeling	• Indicated for short-term and intermittent long-term therapy for mild to moderate atopic dermatitis in non-immunocompromised patients 2 years and older • Not recommended for use in pediatric patients less than 2 years of age. Infants on Elidel Cream had an increased incidence of some adverse events compared to vehicle which included pyrexia, URI, nasopharyngitis, gastroenteritis, otitis media, and diarrhea.	B	Novartis	9/24/2001	
356.	11/16/2001	Calcijex	calcitriol	Management of hypocalcemia in patients undergoing chronic renal dialysis	Labeling	• The safety and effectiveness of calcitriol was examined in a double-blind placebo-controlled trial of 35 pediatric patients (13-18 years of age) with end-stage renal disease and on dialysis. • The primary efficacy endpoint favored the calcitriol-treated versus the placebo-treated patients • Transient hypercalcemia was seen in 1 of 16 calcitriol-treated patients; 6 of 16 (38%) calcitriol-treated patients and 2 of 19 (11%) placebo-treated patients had Ca x P >75	B	Abbott	2/16/2001	
357.	10/10/2001	Derma-Smoothe /FS Topical Oil	fluocinolone	Atopic dermatitis	Labeling	• Approved down to 2 years of age	R	Hill	NA	
358.	10/3/2001	Diprolene AF, Diprosone, Lotrisone	betamethasone;betamethasone/ clotrimazole	Diprolene AF and Diprosone - Relief of inflammatory and pruritic manifestations	Labeling	• Diprolene AF Cream • In an open-label study for the treatment of atopic dermatitis, 19 of 60 (32%) evaluable patients (ages 3 mo-12 years) showed HPA axis suppression. The younger the age group, the greater the proportion of patients with adrenal suppression.	B	Schering	NA	

	Labeling Date♦	Trade Name	Generic or Proper (Biologics●) Name	Indication(s) Studied	Product Labeling	Labeling Changes	BPCA (B)/ PREA (P)/ Rule (R)	Sponsor	PE Granted Date	N N P S
				of corticosteroid-responsive dermatoses Lotrisone-Treatment of symptomatic inflammatory tinea pedis, tinea cruris and tinea corporis		• Indicated in patients 13 years and older. Not recommended in pediatric patients 12 years and younger • Strengthened labeling in Clinical Pharmacology, Precautions- General and Pediatric Use subsections • Local adverse reactions including signs of skin atrophy (telengiectasia, bruising, shininess) occurred in 10% of pediatric patients (3mo-12 years) • Diprosone Cream, Ointment, Lotion • A separate open-label study was performed in pediatric patients with atopic dermatitis for each Diprosone formulation • Testing for HPA axis suppression was positive with each formulation in the age groups studied: Cream - 23% (ages 2yr-12yr); Ointment - 28% (ages 6mo-12yr); and Lotion - 73% (ages 6yr-12yr) • Indicated in patients 13 years and older. Not recommended in pediatric patients 12 years and younger • Strengthened labeling in Clinical Pharmacology, Precautions- General and Pediatric Use subsections • Local adverse reactions including signs of skin atrophy (telengiectasia, bruising, shininess) occurred in the cream and ointment studies • Lotrisone • Not recommended for patients under the age of 17 years and not recommended for diaper dermatitis; previously not recommended for patients under the age of 12 years • In an open-label study of Lotrisone cream for the treatment of tinea pedis, 17 of 43 (39.5%) evaluable patients (ages 12-16 years) demonstrated adrenal suppression as determined by cosyntropin testing • In an open-label study of Lotrisone cream for the treatment of tinea cruris, 8 of 17 (47.1%) evaluable patients (ages 12-16 years) demonstrated adrenal suppression by cosyntropin testing • Indicated in patients 17 years and older				
359.	10/1/2001	Betapace	sotalol	Arrhythmia	Labeling	• Analysis of 2 trials provided information on PK and PD in children 3 days – 12 years; safety and efficacy have not been established • Information on dose, pharmacokinetics and AE's • Pharmacokinetics: BSA most important covariate and more relevant than age • Smaller children (BSA < 0.33 m2) showed tendency for larger change in QTc and increased frequency of prolongation of the QTc interval as well as greater beta-blocking effects • Individualized dosing on a mg/m2 basis • Information on preparation of a suspension	B	Berlex	1/6/2000	
360.	8/28/2001	Topamax Tablets & Sprinkle	topiramate	Seizures associated with Lennox-	Labeling	• Approved for treatment down to 2 years of age	R	R.W. Johnson	NA	

	Labeling Date♦	Trade Name	Generic or Proper (Biologics●) Name	Indication(s) Studied	Product Labeling	Labeling Changes	BPCA (B)/ PREA (P)/ Rule (R)	Sponsor	PE Granted Date	N N P S
		Capsule		Gastaut syndrome						
361.	8/16/2001	Epivir-HBV	lamivudine	Treatment of Chronic Hepatitis B	Labeling	• Safety and effectiveness established down to 2 years • Established a dose of 3mg/kg/day up to a maximum of 100mg/day (adult dose)	B	GlaxoSmith Kline	7/25/2001	
362.	7/19/2001	Buspar	buspirone-	General Anxiety Disorder	Labeling	• Safety and effectiveness were not established in patients 6 to 17 years of age for treatment of General Anxiety Disorder at doses recommended for use in adults • PK parameters (AUC and Cmax) of buspirone and its active metabolite were found to be equal to or higher in children and adolescents than that of adults	B	Bristol-Myers Squibb	5/22/2000	
363.	6/25/2001	Valtrex Caplets	valacyclovir	Treatment of cold sores	Labeling	• New indication approved for use down to 12 years of age	R	GlaxoSmith Kline	NA	
364.	6/6/2001	Mentax Cream	butenafine	Tinea versicolor	Labeling	• Approved down to 12 years of age; previously approved in adults only	R	Bertek	NA	
365.	5/11/2001	Agenerase Capusles and Oral Solution	amprenavir	HIV	Labeling	• Approved for use in combination with other antiretroviral agents; new labeling provides information about the effects of drug-drug interaction	R	GlaxoSmith Kline	NA	
366.	3/30/2001	Ultane	sevoflurane	Induction and maintenance of general anesthesia	Labeling	• New study in pediatric patients 9 days-12 years comparing sevoflurane and halothane • Precautions section and Adverse Events During Post-Marketing subsection updated to add information on the rare cases of seizures that have been reported in pediatric patients in association with sevoflurane use. The majority of cases were in children and young adults, most of whom had no medical history of seizures • Pediatric information consolidated into new Pediatric Use subsection	B	Abbott	8/2/2000	
367.	3/27/2001	Nasalcrom	cromolyn	Prevention and relief of nasal symptoms of hay fever and other nasal allergies	Labeling	• Established proper dose in 2 year - 6 year olds and provided additional safety and compliance data for this age group	B	Pharmacia & UpJohn	11/2/1999	
368.	2/23/2001	Diprivan	propofol	Induction and/or maintenance of anesthesia	Labeling	• Maintenance of anesthesia- age decreased down to 2 months from 3 years • Induction of anesthesia remains the same- 3 years of age and above • Concomitant administration with fentanyl may result in serious bradycardia • Abrupt discontinuation following prolonged infusion may result in flushing of hands and feet, agitation, tremulousness and hyperirritability	B	AstraZeneca	8/11/1999	

	Labeling Date♦	Trade Name	Generic or Proper (Biologics●) Name	Indication(s) Studied	Product Labeling	Labeling Changes	BPCA (B)/ PREA (P)/ Rule (R)	Sponsor	PE Granted Date	N N P S
						• Propofol is not indicated for pediatric ICU sedation as safety has not been established. In a single multicenter trial of ICU sedation in critically ill pediatric patients (patients with upper respiratory tract infections excluded), the incidence of mortality (causality not established) was 9% in the propofol arm versus 4% in the standard sedative agents arm				
369.	2/21/2001	Infuvite Pediatric	multivitamin infusion	Daily multivitamin maintenance	Labeling	• Approved for infants down to newborn	R	Sabex, Inc.	NA	
370.	2/13/2001	Vasotec	enalapril	Hypertension	Labeling	• Labeling for 1 month-16 years of age • Information on dose, efficacy and pharmacokinetics • Information on preparation of a suspension	B	Merck	2/2/2000	
371.	12/21/2000	Benzaclin	benzoyl peroxide; clindamycin phosphate	Acne vulgaris	Labeling	• Approved down to 12 years of age	R	Sanofi Aventis	NA	
372.	12/20/2000	CellCept	mycophenylate	Prophylaxis of organ rejection in renal transplant patients	Labeling	• Approved for use down to 3 months of age as a combination regimen with cyclosporine and corticosteroids	R	Hoffman-LaRoche	NA	
373.	12/15/2000	Glucophage (immediate release)	metformin	Diabetes Mellitus	Labeling	• Safety and effectiveness as monotherapy established in patients 10-16 years of age	B	Bristol-Myers Squibb	3/15/2000	
374.	12/14/2000	TamiFlu	oseltamivir	Treatment of uncomplicated acute illness due to influenza	Labeling	• Safety and effectiveness established for treatment in patients 1-12 years of age • The safety and effectiveness in pediatric patients younger than 1 year of age have not been established • Safety and effectiveness for prophylaxis in pediatric patients younger than 13 years of age have not been established (Note: labeled for prophylaxis down to 1 year due to PREA on 12/21/2005) • The adverse event profile in adolescents is similar to that for adults and pediatric patients aged 1 to 12 years • Information on dosing, PK parameters, AE profile, and clinical studies	B	Roche	NA	
375.	12/11/2000	Maxalt and Maxalt-MLT	rizatriptan	Migraine		• Summary pending	R	Merck	NA	
376.	12/8/2000	Protopic Ointment	tacrolimus	Atopic dermatitis	Labeling	• Approved down to 2 years of age; lower dose of 0.03% twice daily	R	Fujisawa	NA	

	Labeling Date♦	Trade Name	Generic or Proper (Biologics●) Name	Indication(s) Studied	Product Labeling	Labeling Changes	BPCA (B)/ PREA (P)/ Rule (R)	Sponsor	PE Granted Date	N N P S
						recommended for patients 2-15 years of age				
377.	12/4/2000	Claritin	loratadine-	Allergic rhinitis/Urticaria	Labeling	• Labeling for 2 - 5 year olds including information on dose, PK parameters and AE profile • PK parameter in 2-5 year olds given a 5mg dose was comparable to the 10mg dose in children 6 years to adolescence	B	Schering	8/14/2000	
378.	11/27/2000	Benzamycin Pak	erythromycin-benzoyl peroxide	Acne vulgaris	Labeling	• Approved down to 12 years of age	R	Dermik Laboratories, Inc.	NA	
379.	11/27/2000	Clindagel	clindamycin topical gel	Acne vulgaris	Labeling	• Approved down to 12 years of age	R	Target Research Associates	NA	
380.	11/17/2000	Tamiflu Capsule	oseltamivir	Prophylaxis of influenza A and B	Labeling	• Approved for prophylactic use down to 13 years of age	R	Roche	NA	
381.	11/14/2000	Trizivir Tablets	abacavir, lamivudine, zidovudine	HIV	Labeling	• Approved in adults and adolescents weighing ≥ 40kg	R	GlaxoSmith Kline	NA	
382.	10/27/2000	Atrovent Nasal Spray	ipratropium	Rhinorrhea		• Approved down to 5 years of age	R	Boehringer Ingelheim	NA	
383.	10/12/2000	Neurontin	gabapentin	Adjunctive therapy in the treatment of partial seizures	Labeling	• Safety and effectiveness established down to 3 years • Neuropsychiatric AE's identified in 3-12 year olds • Oral clearance normalized per body weight increased in children <5 years • Higher doses of gabapentin required in children <5 years	B	Parke-Davis	2/2/2000	
384.	9/29/2000	Flovent Diskus Inhalation Powder	fluticasone	Asthma	Labeling	• Approved down to 4 years of age; new delivery system	R	GlaxoSmith Kline	NA	
385.	8/25/2000	Lac-Hydrin	ammonium lactate	Xerosis, ichthyosis	Labeling	• Safety and effectiveness established in patients 2 – 11 years of age; previously approved ³12 years of age	B	Westwood-Squibb	10/1/1999	
386.	8/24/2000	Advair Diskus	fluticasone/ salmeterol	Asthma	Labeling	• Approved down to 12 years of age	R	GlaxoSmith Kline	NA	
387.	8/21/2000	Unithroid Tablets	levothyroxine	Hypothyroidism	Labeling	• Approved down to the newborn	R	Jerome Stevens	NA	
388.	8/11/2000	Lodine	etodolac	Relief of signs & symptoms of Juvenile Rheumatoid Arthritis	Labeling	• New indication in 6 years -16 years • Higher dose (per kg basis) in younger children which is approximately 2 times the lower dose recommended for adults	B	Wyeth Ayerst	12/6/1999	

	Labeling Date♦	Trade Name	Generic or Proper (Biologics●) Name	Indication(s) Studied	Product Labeling	Labeling Changes	BPCA (B)/ PREA (P)/ Rule (R)	Sponsor	PE Granted Date	NNPS
389.	8/1/2000	Concerta Extended Release Tablets	methylphenidate	ADHD	Labeling	• Efficacy established down to 6 years of age	R	Alza	NA	
390.	8/1/2000	Motrin Suspension	ibuprofen/ pseudoephedrine	Temporary relief of nasal and sinus congestion, minor body aches and pains, fever, stuffy nose, headache and sore throat	Labeling	• Information on the over-the-counter use in pediatric patients 2 to 11 years of age	B	McNeil	NA	
391.	7/27/2000	Vaniqa Cream	eflornithine	Reduction of facial hair in females	Labeling	• Approved for female patients down to 12 years of age	R	Bristol-Myers Squibb	NA	
392.	7/14/2000	ChloraPrep OneStep OTC	chlorhexidine/ isopropyl alcohol	Skin preparation prior to surgery		• New indication approved down to 2 months of age; Warning: do not use in less than 2 months of age	R	Medi-Flex Hospital Products	NA	
393.	7/14/2000	Malarone	atovaquone/ proguanil	Treatment of malaria	Labeling	• Safety and efficacy for treatment of malaria established down to5 kg. • Attributable AE occurring in ≥ 5% of the pediatric patients (5-< 11 kg) was diarrhea (6%) • Malarone tablets may be crushed and mixed with condensed milk just prior to administration for children who may have difficulty swallowing. • The apparent clearance (CL/F) of both atovaquone and proguanil are related to body weight	B	Glaxo Wellcome	8/6/2003	
394.	6/16/2000	AmBisome Injection	amphotericin B	Cryptococcal meningitis in HIV infected patients	Labeling	• New indication approved down to 1 year of age; established a dose of 6mg/kg/day	R	Fujisawa	NA	
395.	5/26/2000	Differin Cream	adapalene	Acne vulgaris	Labeling	• Approved down to 12 years of age	R	Galderma	NA	
396.	5/22/2000	Optivar	azelastine	Itching associated with Allergic Conjunctivitis	Labeling	• Safety and effectiveness established down to 3 years	B	Muro Pharma/Asta Medica	8/11/1999	
397.	4/26/2000	Relenza Rotadisk	zanamivir	Treatment of Influenza A and B	Labeling	• Approved down to 7 years of age	R	GlaxoSmith Kline	NA	
398.	4/20/2000	Lantus	insulin glargine	Type 1 Diabetes	Labeling	• Safety and effectiveness established down to 6 years	B	Aventis	7/12/1999	
399.	4/12/2000	Trivagizole 3 Vaginal Cream	clotrimazole	Vaginal yeast infection	Labeling	• Approved for OTC use in patients 12 years of age and older	R	Taro	NA	

	Labeling Date♦	Trade Name	Generic or Proper (Biologics●) Name	Indication(s) Studied	Product Labeling	Labeling Changes	BPCA (B)/ PREA (P)/ Rule (R)	Sponsor	PE Granted Date	N N P S
400.	4/4/2000	Humalog Injection	insulin lispro	Type 1 diabetes	Labeling	• Approved for use in the pediatric population; instructions on use of the diluted product in the pediatric population	R	Lilly	NA	
401.	3/17/2000	Lamisil AT Spray Pump	terbinafine	Jock itch, athletes foot, ringworm	Labeling	• Approved for OTC use	R	Novartis	NA	
402.	2/4/2000	Tri-Nasal Spray	triamcinolone	Allergic rhinitis	Labeling	• Approved down to 12 years of age	R	Muro	NA	
403.	1/12/2000	Advil	ibuprofen	Fever, minor aches & pain, cold symptoms	Labeling	• Extended age range from 2 years to 6 months for the over-the-counter use based on a large safety database (14,291 patients)	B	Whitehall	7/1/1998	
404.	12/8/1999	Alocril	nedocromil	Allergic Conjunctivitis	Labeling	• Approved down to 3 years of age	R	Allergan	NA	
405.	11/8/1999	Omnicef	cefdinir	Bronchitis	Labeling	• Approved for use in adolescents	R	Abbott	NA	
406.	10/22/1999	Zantac	ranitidine	Gastroesophageal Reflux	Labeling	• Small studies in newborns 0 to 1 month receiving ECMO did not demonstrate efficacy but provided information on dose and PK	B	Glaxo	1/19/1999	
407.	9/24/1999	Alamast	pemirolast	Allergic Conjunctivitis	Labeling	• Safety and effectiveness established down to 3 years	B	Santen	8/11/1999	
408.	9/17/1999	Accolate Tablets	zafirlukast	Prophylaxis and chronic treatment of asthma	Labeling	• Approved down to 7 years of age; efficacy extrapolated from demonstrated efficacy in patients 15 years and older	R	AstraZeneca	NA	
409.	8/24/1999	Ceftin Oral Suspension	cefuroxime	Acute bacterial sinusitis		• Approved down to 3 years of age	R	Lifecycle Ventures	NA	
410.	8/18/1999	Derma-Smoothe /FS Topical Oil	fluocinolone	Atopic dermatitis	Labeling	• Approved down to 6 years of age; previously approved in adults only	R	Hill	NA	
411.	7/26/1999	Relenza Rotadisk	zanamivir	Treatment of influenza A and B	Labeling	• New indication approved down to 12 years of age	R	GlaxoSmith Kline	NA	
412.	7/23/1999	Topamax Tablets	topiramate	Adjunctive treatment of partial onset seizures and generalized tonic clonic seizures	Labeling	• Approved down to 2 years of age	R	Ortho-McNeil	NA	
413.	7/14/1999	Omnicef	cefdinir	Otitis media	Labeling	• Approved 5-day treatment regimen; previously labeled for a 5-10 day	R	Abbott	NA	

	Labeling Date♦	Trade Name	Generic or Proper (Biologics●) Name	Indication(s) Studied	Product Labeling	Labeling Changes	BPCA (B)/ PREA (P)/ Rule (R)	Sponsor	PE Granted Date	NNPS
						treatment regimen				
414.	7/9/1999	Tagamet HB 200 Liquid OTC	cimetidine	Heartburn and indigestion	Labeling	• New indication approved down to 12 years of age; new OTC suspension	R	GlaxoSmith Kline	NA	
415.	7/2/1999	Zaditor Ophthalmic Soln.	ketotifen fumarate	Allergic conjunctivitis	Labeling	• Approved down to 3 years of age; efficacy extrapolated from adult data	R	Novartis	NA	
416.	6/17/1999	Cutivate Cream	fluticasone proprionate	Treatment of corticosteroid responsive dermatoses	Labeling	• Extended the age range from 5 years down to 3 months of age	R	Elan	NA	
417.	4/15/1999	Motrin	ibuprofen	Fever, minor aches & pain, cold symptoms	Labeling	• Extended age range from 2 years to 6 months for the over-the-counter use based on a large safety database (27,000 patients)	B	McNeil	7/1/1998	
418.	12/17/1998	Ziagen	abacavir	HIV infection	Labeling	• Labeling for 3 months - 12 years • Information on dose, efficacy, PK parameters and AE profile	B	GlaxoSmith Kline	12/14/1998	
419.	10/15/1998	Versed	midazolam	Sedation/anxiolysis/ amnesia	Labeling	• Specified the effective dose, effective dose range, and time of onset • Defined volume of distribution and similarity to adult protein binding and elimination • Additional information on AE's and warnings about concomitant medications • Identified a subpopulation (children with congenital heart disease and pulmonary hypertension) at higher risk for AE's and the need to start therapy at the lower end of the dosing range	B	Roche	9/18/1998	
420.	2/10/1998	Amerge	naratriptan	Migraine	Labeling	• Summary pending	R	Glaxo Wellcome	NA	

Legend:
Products marked with a (#) are for labeling changes that were not based on information from clinical trials in pediatric patients.
*Simultaneous pediatric and adult approval in original NDA
♦This label only reflects the pediatric changes for studies submitted in response to a Written Request and is not necessarily the most current label

§ - Partial response to Written Request
▪ NME studied and approved in pediatric population first
WD – Withdrawn from market